Professor Joshua D. Sarnoff submits the following comments in regard to the "Call for submission, Special Rapporteur on toxics and human rights; Upcoming thematic report on the right to benefit from scientific progress and its applications" ("Call" and "Report"). Professor Sarnoff teaches intellectual property, administrative, and climate law at DePaul University College of Law, and has written about many topics relating to the human right to benefit from scientific progress. Although the comments focus on the right to access the benefits of science in regard to health care and climate change and on barriers to access from intellectual property rights, it notes a few points of intersection with hazardous waste and production concerns.

Summary

The remit of the Special Rapporteur is primarily focused on toxic chemicals, and the Call notes the plan to focus the Report on "the interface between information, science, and hazardous substances and wastes." However, the concerns posed by the Call and Report are much broader. As the Call notes, "[t]he right to science encloses all scientific disciplines. It encompasses enabling access for all without discrimination to the benefits of science and its impacts for the full enjoyment of all human rights, including the right to life, the right to health, the right to body integrity and the right to education." These concerns regarding scientific benefits and disciplines are clearly not limited to "hazardous substances and wastes," as should be evident from the COVID-19 pandemic and worldwide responses to it.

This submission therefore focuses on the Article 15(1) International Covenant on Economic, Social and Cultural Rights ("ICESCR") "recognition of the right of everyone … (a) To take part in cultural life; (b) To enjoy the benefits of scientific progress and its application; [and] (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." It expands the focus of the Report by noting the many ways that the public may be deprived of such rights and progress by intellectual property rights, in regard to: the current COVID-19 pandemic (and likely future pandemics absent significant change to our worldwide health systems and to our continued reliance on market mechanisms to provide for the rights to life and health); climate change (regardless of whether or not one views greenhouse gases – "GHGs" – as "hazardous substances" and regulates them as such under laws like the U.S. Clean Air Act); and other critical social concerns. In particular, the submission implicitly responds to four aspects of the Call: "Enabling the access to the right to information and scientific evidence, and environmental and human rights assessment as preconditions for the full enjoyment of the right to science"; "Examples of good and bad practices by governmental entities and business enterprises for promoting or hindering scientific progress or the wide availability of results of scientific work"; "Mechanisms for international cooperation on scientific exchange"; and "Means to enhance

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technology transfer and institutional strengthening in developing countries, including with regard to access to funding to ensure scientific process."

The submission notes as follows:

(1) the need to address in the context of COVID-19 and likely future pandemics nationalist controls over information and scientific health-related products, and the need to alter reliance on market mechanisms and intellectual property rights, so as to assure that all publics – particularly those in developing countries – can benefit from the rights to enjoy the benefits of scientific progress and its applications so as to effectuate the rights to life and to health;
(2) the similar need to address intellectual property rights in regard to climate change mitigation and adaptation (including carbon dioxide removal and solar radiation management technologies);
(3) the need to address rights to genetic sequencing information and data ownership so as to better effectuate rights to life and health, and more broadly the need to mandate open science and open data to effectuate rights to life, health and (particularly) education, as well as to foster scientific progress;
(4) the need to assure access to medicines and to address other health care and pricing concerns of reliance on intellectual property rights and private markets, including resurrecting efforts to adopt an international research and development ("R&D") treaty; and
(5) the need to better assure benefits sharing with scientists and to address the structure of scientists' compensation and non-competition restrictions so as to better incentivize innovation and to better effectuate the right to the moral and material interests of the scientists on whom we rely for needed technological developments.

All of these areas pose significant problems for the various rights of the public and of scientists themselves, absent substantial changes to the way business as usual has been conducted. Changing the existing systems will be extremely difficult and will be vigorously resisted by vested interests. The most significant problem to address is the rhetoric of counter-narratives to protecting the right of the public to benefit from science and its applications. The most pervasive and persuasive counter-narrative is that any changes to our current reliance on intellectual property rights and private markets for development and dissemination of needed technologies will damage investment and reduce innovation and thereby impede rather than promote the progress of science and limit the benefits of its applications. Further counter-narratives treat any such changes as requiring "inappropriate" government intervention in private markets, which interferes with purportedly fundamental or at least vested rights of scientists and private investors. These counter-narratives, however, fail to focus adequately on *duties* of scientists and of private investors or on the corresponding *harms* to the rights of the public – including to benefit from such scientific and cultural progress and their applications – which result from privileging the private and property interests highlighted by the counter-narratives. The Report should identify these concerns and recommend significant changes to assure that the public is able to obtain benefits that are recognized rights under the ICESCR.

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1. Pandemics, Product Nationalism, and Information Sharing.

As Professor Peter Yu has previously noted, "In response to this global [COVID-19] pandemic, international intergovernmental bodies quickly mobilized to coordinate efforts to promote access to vaccines, diagnostic kits, therapeutic treatments, medical devices, and other health technologies." Peter K. Yu, *Modalities, Challenges, and Possibilities: An Introduction to the Pharmaceutical Innovation Symposium*, 7 TEX. A&M J. PROP. L. 1, 23 (2021). These measures included the World Health Organization ("WHO") creation of the COVAX facility to purchase and distribute vaccines that would be developed and the ACT Accelerator and Covid Technology Access Pool ("C-TAP") to facilitate technology development and transfer through private contributions to a patent pool and voluntary licensing arrangements. Similarly, countries and researchers early-on shared information about the genetic sequences of various COVID-19 variants and about disease etiology and effects to facilitate vaccine development, public health containment, and disease treatment, even though numerous mistaken judgments were made (e.g., beliefs regarding the principle means of COVID-19 spread being from fomites rather than from aersols). *Compare, e.g.,* Ian de Guillou, *COVID-19: How unprecedented data sharing has led to faster-than-ever outbreak research,* HORIZON: The EU Research & Innovation Magazine (23 Mar. 2020), https://horizon-magazine.eu/article/covid-19-how-unprecedented-data-sharing-has-led-faster-ever-outbreak-research.html ("Advances in gene sequencing have allowed scientists to trace and monitor the COVID-19 pandemic faster than any previous outbreak. However, gaps in our knowledge of how coronaviruses work has made it difficult to understand what makes the new coronavirus special.") *with* Richard van Noorden, *Scientists call for fully open sharing of coronavirus genome data,* NATURE (3 Feb. 2021), https://www.nature.com/articles/d41586-021-00305-7 ("Hundreds of scientists are urging that SARS-CoV-2 genome data should be shared more openly to help analyse how viral variants are spreading around the world.").

As paragraph 82 of General Comment No. 25 has noted, "[p]andemics are a crucial example of the need for scientific international cooperation to face transnational threats ..." The cooperative, voluntary sharing of such scientific information and genetic data was what facilitated the rapid development of diagnostic tests and vaccines. In contrast, it would have significantly retarded such developments (and the opportunity costs of such delays would have resulted in massively increased death and disease), if the norms of scientific sharing in a pandemic had been replaced with a regime of tight private controls over such information and data as trade secrets or confidential know-how or as protected intellectual property such as data rights. As discussed further below, the sharing of scientific information did not extend to the development of the products themselves for large-scale manufacturing, not only for treatments such as Remdesivir or the various mRNA or adenovirus vaccines and the input patented and trade-secret technologies, but also for personal protective equipment, medical equipment such as ventilators, and other needed applications of science and its applications.

In contrast to international scientific sharing efforts regarding the virus itself and its genetic sequences, many national governments in technologically developed countries successfully

funded the development of numerous vaccines that were brought to market and obtained regulatory approvals in record time. In contrast, measures to develop therapeutics have been slower. *See, e.g.,* Regulatory Focus (04 June 2021), https://www.raps.org/news-and-articles/news-articles/2020/3/covid-19-therapeutics-tracker ("More than a year into the pandemic, only a handful of repurposed therapeutics have been approved to treat COVID-19: dexamethasone in the UK and Japan; Avigan (favilavir) in China, Italy and Russia; and Veklury (remdesivir) in the US, UK and Japan."). Diagnostics were more rapidly developed, but typically do not require such extensive investments for clinical trials nor as rigorous regulatory approvals. Although significant private investments were also made in such vaccine and some therapeutics developments, some of the risk of such investments were reduced by governmental pre-purchase agreements and funding for development.

Significantly, these funding agreements typically assured: (1) that private vaccine and therapeutic developers receiving such funds could retain rights in their data, methods, clinical data, and intellectual property (collective "IPR") that might be employed or developed in generating such regulatorily approved products; and (2) provided for priority purchases of vaccine or therapeutic supplies that could be produced by the private rights holders. Simply put, these proprietary measures to control the technologies and their ability to be produced by third-parties around the world have proved to be *catastrophic* in their consequences, resulting in vaccine and therapeutic nationalism and inadequate supplies resulting from the failure to share scientific information, know-how, and rights to produce and gain regulatory approval for the needed products in other countries. Hence, WHO Director General Tedros Adhanom Ghebreyesus politely urged vaccine-rich governments to do more for vaccine-poor people: "it's regrettable that some countries continue to prioritise vaccinating younger, healthier adults at lower risk of disease in their own populations, ahead of health workers and older people elsewhere." The less polite way of putting this is that by prioritizing their own populations by "clearing the shelves" of available supplies, the vaccine-rich governments *have caused* (not just permitted) greater worldwide deaths and increased variant developments from the greater replication rates that could have been reduced by prioritized worldwide distribution.

In regard to manufacturing restrictions resulting from such IPR, numerous countries have sought to have the World Trade Organization ("WTO") adopt a waiver of the intellectual property rights obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), originally in regard to all relevant IPRs relating to addressing "prevention, containment, or treatment" of COVID-19 for an unspecified number of years, and in a subsequent revision limited to "health products and technologies" relating thereto, for a minimum of 3 years until a subsequent declaration to terminate the waiver. See WTO/IP/C/W/669 ("The obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement, shall be waived in relation to prevention, containment or treatment of COVID-19, for [X] years from the decision of the General Council"); WTO/IP/C/W/669, Rev. 1 ("health products and technologies including diagnostics, therapeutics, vaccines, medical devices, personal protective equipment, their materials or components, and their methods and means of manufacture for the prevention, treatment or containment of COVID-19"; "This waiver shall

be in force for at least 3 years from the date of this decision. The General Council shall, thereafter, review the existence of the exceptional circumstances justifying the waiver, and if such circumstances cease to exist, the General Council shall determine the date of termination of the waiver"; "Members shall not challenge any measures taken in conformity with the provision of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994, or through the WTO's Dispute Settlement Mechanism."). An adopted waiver thus would then prevent countries from bringing complaints against other countries under the WTO's Dispute Settlement Agreement. But for most countries, the waiver would need to be followed by legislative or other governmental actions to be effectuated under domestic laws, in order to relax existing strictures adopted to effectuate the pre-waiver requirements. As a practical matter, the waiver would also as a matter of diplomacy make much more untenable efforts of some countries to penalize others (typically through trade sanctions but also through numerous other informal means, including cutting foreign aid or other cooperative measures) that would choose under their domestic laws to override (with or without compensating private rights holders) the TRIPS obligations to create and enforce intellectual property rights including patents, trade secrets, etc.

Most importantly, notwithstanding the general premise of the patent system to provide exclusive rights in exchange for the right to "make and use" the invention, it has become clear that for many needed COVID-19 technologies such disclosures (once they become public 18 months after filing for protection, as only a few such COVID-19-specific patents have yet issued) may be in adequate to transfer the needed information to make and use patented inventions at the needed commercial production scale. Patented input technologies to such vaccine manufacturing similarly may not disclose the needed trade secrets or know-how to permit widespread (and competitive) manufacturing around the world of the needed vaccines that now have been developed. Some vaccine developers have chosen to (and should be commended for) voluntarily license(ing) their trade secrets and know-how to expand manufacturing (presumably subject to stringent and confidential restrictions to assure that such information is not publicly disclosed and not used for other research, development, or manufacturing efforts). But such voluntary licensing has proven unable to provide vaccine production to satisfy the worldwide demand, and the consequence of pre-purchasing the limited supplies it that numerous countries have yet to receive anywhere near the doses that they need while other countries have vaccinated most of their riskiest groups within their domestic populations. *See, e.g.,* Heidi Ledford, *Six months of COVID vaccines: what 1.7 billion doses have taught scientists,* NATURE (4 June 2021), https://www.nature.com/articles/d41586-021-01505-x ("for much of the world — particularly low- and middle-income countries — limited supplies mean that vaccines will probably have little impact on the course of the pandemic this year. Madhi says that he does not expect the current roll-out in South Africa to do much to protect it from the impending third surge there: by the time all people over the age of 60 have been offered their first dose at the end of June, he expects social distancing and other measures to have already brought the country's burgeoning infection numbers down. And in India, a combination of low vaccination rates, aggressive variants and widespread social interaction are thought to have led to its tragic and overwhelming COVID-19 outbreak. Whereas some wealthy countries were able to pre-order large amounts of vaccine, many low-

and middle-income countries have had to make do with less. The World Health Organization's target is to vaccinate 20% of the population in those countries by the end of this year. "This is not going to be the main exit strategy for them this year," says Mark Jit, an infectious-disease modeller at the London School of Hygiene & Tropical Medicine. "Maybe in 2022, when the supply is less constrained." Instead, such countries might need to rely heavily on social distancing, mask wearing and test-and-trace programmes."). Even without final product hoarding, countries are controlling needed supplies of products and reagents that would permit other countries to produce vaccines that are needed. *See, e.g.,* Ludwig Burger & Francesco Guarascio, *EU persuades U.S. to ease COVID export restrictions for CureVac-sources,* REUTERS (21 May 2021), https://www.reuters.com/world/us/eu-persuades-us-ease-covid-export-restrictions-curevac-sources-2021-05-21/. Further, like for vaccines, therapeutics have been hoarded by countries for their own populations. *See, e.g.,* Judy Stone, *US Buys World Supply Of Remdesivir For Coronavirus- What Does That Mean For Public Health And Our Future?,* Forbes (2 July 2020), https://www.forbes.com/sites/judystone/2020/07/02/us-buys-world-supply-of-remdesivir-for-coronaviruswhat-does-that-mean-for-public-health-and-our-future/?sh=f99a97d16e99. In short, this has become a "war" of nations, rather than an international cooperative effort to research, produce and distribute in a cooperative worldwide fashion.

Of particular relevance to the remit of the Special Rapporteur, in regard to needed medical equipment, it was clear at an early stage of the pandemic in regard to ventilators that much more was needed in regard to product repairs in the absence of adequate product manufacturing. There was a significant degree of voluntary pledging of intellectual property rights (including copyrights) that permitted authorized 3D printing of repair parts. Conversely, there was likely a substantial amount of unauthorized production of such needed equipment, demonstrating that were intellectual property rights actually enforced against such production it would have had significant adverse consequences. Absent such repair, the needed products would have been disposed and become part of the waste stream, and additional resources would have had to be used to develop substitutes (but not in the needed time-frames to save lives). Accordingly, there is a substantial need for a right to repair necessary products of the applications of science so as to assure the rights to life and health, while simultaneously reducing the waste burdens of society that also adversely affect the rights to live and health. I have discussed the need to adopt such repair rights by domestic legislation, noting that the domestic measures may be fully compliant with the TRIPS Agreement, but that pre-authorization by domestic legislation of third-party rights to produce new devices in emergencies might require some further amendment to the TRIPS Agreement. *See* https://www.traderxreport.com/covid-19/trips-covid-19-and-the-right-to-repair-and-produce-needed-medical-products-in-emergencies-part-1-of-2/; https://www.traderxreport.com/covid-19/trips-covid-19-and-the-right-to-repair-and-produce-needed-medical-products-in-emergencies-part-2-of-2/.

Accordingly, it has become clear that governments must do more to require sharing of scientific information, know-how and trade secrets among private researchers and companies that make R&D efforts and investments, as well as with other governmental scientists and regulators, to

facilitate and where needed to compel international cooperative production efforts, and to prevent nationalism in regard to development, manufacturing and hoarding of needed products. Again, the prioritized access is not limited to final vaccine products, but also includes inputs to such products (which have been subject to export controls) and all other pandemic-related needs. The consequence of failing to do so is to adversely affect the rights of health and life around the world, for billions of the world's peoples. This simply is the most important issue that the world may currently face in the short term. The proposals calling for negotiations to develop a new pandemic treaty within the WHO are a welcome step in the right direction. But resistance to changing the overall structure of the existing health and innovation ecosystems will be substantial, particularly as it may interfere with private investment returns and reliance on private entities and markets to develop and produce the needed technologies. To the extent that such measures may decrease private innovation funding for R&D and manufacturing, there are numerous means for governments to remedy such funding deficits other than reliance on intellectual property rights and private markets. *See, e.g.,* Joshua D. Sarnoff, *Government Choices in Innovation Funding (with Reference to Climate Change),* 62 EMORY L.J. 1087 (2013); Joshua D. Sarnoff, *The Likely Mismatch Between Federal R&D Funding and Desired Innovation,* 18 VANDERBILT JOURNAL OF ENTERTAINMENT AND TECHNOLOGY LAW 363 (2016).

There is also significant tension between the ICESCR Article 15 obligations for the public to benefit from scientific developments and applications and scientists 'moral and materials rights to benefit from their scientific discoveries and creative applications. *See generally* Audrey R. Chapman, *Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and its Applications,* 8 J. HUM. RIGHTS 1 (2009). But little is said about scientists' duties as opposed to rights. I have written about extensively, there were historic duties of scientists to share freely with the public their discoveries of nature and science, which grounded in patent systems around the world various exclusions from private property in such discoveries by limiting patent eligible subject matter. *See, e.g.,* Joshua D. Sarnoff, *Religious and Moral Grounds for Patent Eligible Subject Matter Exclusions*, in PATENTS ON LIFE (Thomas Berg et al. eds., Cambridge U. Press 2019); Joshua D. Sarnoff, *Patent Eligible Inventions After* Bilski: *History and Theory*, 63 HASTINGS L.J. 53 (2011).

In contrast, very little has been said about potential state responsibility and liability for COVID-19 or any other pandemic disease. Much has been made about the possible origins of the virus as originating from Chinese laboratories or wet markets. Perhaps state responsibility and state liability might pose additional impetus to greater protective measures against the development of pandemic diseases in the first instance. As the UN Resolution on Permanent Sovereignty Over Natural Resources declared that natural resources are the property of the states where they originate, one can view such pandemic organisms such as viruses or bacteria like ferae naturae, for which strict liability would attach to the harm they cause when they escape control of the owner. Further discussion of state liability and state responsibility for pandemic disease needs to be addressed, particularly in its relationship to whether individuals may have legal claims for violation of their rights to health, life, etc. as a result of pandemic disease that a nation-state could have controlled or otherwise prevented from occurring. How else would those rights be adequately effectuated once the rights are violated?

2. Climate-change-related technologies and pollution.

As I have written about extensively, intellectual property rights will affect the nature of technology development and transfer to address climate change. *See, e.g.,* RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND CLIMATE CHANGE (Joshua D. Sarnoff, ed., Edward Elgar Press 2016); Joshua D. Sarnoff & Margaret Chon, *Innovation Law and Policy Choices for Climate Change-Related Public-Private Partnerships*, in GLOBAL INTELLECTUAL PROPERTY, PUBLIC-PRIVATE PARTNERSHIPS, AND SUSTAINABLE DEVELOPMENT GOALS (Cambridge U. Press Pedro Roffe et al. eds 2018); Jesse Reynolds, Jorge L. Contreras & Joshua D. Sarnoff, *Solar Climate Engineering and Intellectual Property: Toward a Research Commons*, 18 MINN. J. OF L. SCI. & TECH. 1 (2017); *Intellectual property rights and new climate change technologies,* in THE OXFORD HANDBOOK OF INTERNATIONAL CLIMATE CHANGE LAW (Kevin R. Gray, Richard Tarasofsky & Cinnamon P. Carlarne eds., Oxford U. Press 2016); Joshua D. Sarnoff, *The Patent System and Climate Change,* 16 VIRGINIA J. L. & TECH. 301 **(**2011). Not only will such IPR potentially result in reduced R&D or needed product manufacturing, but also will increase the costs of access to needed mitigation and adaptation technologies (including carbon dioxide removal and solar radiation management technologies). By doing so, it will also require payments for technological access to products (if available) that run counter to the obligations of the United Nations Framework Convention on Climate Change – specifically Article 3.1. UNFCCC, Art. 3.1 ("The Parties should protect the climate system for the benefit of present and future generations of humankind, on the basis of equity and in accordance with their common but differentiated responsibilities and respective capabilities. Accordingly, the developed country Parties should take the lead in combating climate change and the adverse effects thereof.").

Intellectual property rights have been a controversial issue within the context of UNFCCC negotiations, precisely because of the same reliance on private investment, market approaches, and minimized government regulation and technology development that has been described above in regard to COVID-19. Not only will climate change cause significant – if not catastrophic – problems in its own right, increased temperatures will also generate greater incidence of pandemic diseases. Accordingly, more attention is needed to assure the right to health and to life in regard to climate change is not impeded by IPR and that the public can properly benefit from the scientific developments that will be generated around the world. Again, if worldwide efforts to promote cooperative R&D and production and international sharing of IPR reduce private investments, governments have numerous means to counteract such measures. And again, further discussion of scientific and private entity duties to the public need to be addressed.

3. Gene sequencing, IPRs, data ownership, open science, and open data.

Outside of the context of pandemics, the narrative of the need for IPRs to generate innovation for the public to benefit from scientific research also is extremely strong in regard to genetic sequencing and biotechnology more generally. This is particularly the case in regard to patent rights on diagnostics, as in the United States such diagnostics have (since the mid-2010s) often been found not to constitute "inventions" that are "patent eligible subject matter." *See, e.g.,*

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Troy Groetken & Bradley Loren, *Rethinking the Way We Patent Diagnostics,* IP Watchdog (Aug. 13, 2020) ("'*Mayo* changed the way courts analyze diagnostic method claims. While the machine-or-transformation test can be a useful analysis tool, it is no longer dispositive.'"), https://www.ipwatchdog.com/2020/08/13/rethinking-way-patent-diagnostics/id=124063/. *Cf.* Joshua D. Sarnoff, *Patent Eligible Medical and Biotechnology Inventions After* Bilski, Prometheus, *and* Myriad*,* 19 TEXAS INTELL. PROP. L.J. 393 (2011).

In contrast, contrary to the narrative that IPRs facilitate R&D, patent rights in research tools and similar medical technologies have actually impeded innovation and public access to needed treatments in a number of areas. *See, e.g.,* Tania Bubela et al., *The mouse that trolled: the long and tortuous history of a gene mutation patent that became an expensive impediment to Alzheimer's research,* 2(2) J. L. & BIOSCIENCES 213 (Nov. 8, 2015). *Cf.* Joshua D. Sarnoff, *The patent law Duchy of Grand Fenwick: a comment on* The mouse that trolled: the long and tortuous history of a gene mutation patent that became an expensive impediment to Alzheimer's research, 2(3) J. L. & BIOSCIENCES 723 (Nov. 2015). How much foregone innovation has resulted from IPRs and their enforcement is incapable of measurement, but rhetorically the opportunity costs of such losses typically is much less salient to decisionmakers and to the public than the tangible benefits of produced inventions that are subject to IPRs.

Further, patent rights have often led to exclusively generated data and databases (which are independently valuable), and consequently to intellectual property rights in such data that further exacerbate these problems. *See, e.g.,* Brenda M. Simon & Ted Sichelman, *Data-Generating Patents,* 111 NW. U. L. REV. 377 (2017). Such measures decrease competition and may generate effective monopolies in the data that such inventions generate, which diminishes competitive development of new data from alternative sources (including potentially of better or at least interoperable databases) and increases costs to the public, diminishing health care access and affordability. This is similar to the concerns that arose from the lack of second opinion diagnoses resulting from the patenting of breast cancer genes, and may thereby also lead to adverse health care outcomes, diminishing effectuation of the rights to health and life. *See, e.g., Myriad reasons to block gene patents: our view,* USA Today (14 Apr. 2013) ("The gene patent also compromises patients' ability to get a second opinion. Myriad grants permission to some labs to conduct "confirmatory tests," but Ellen Matloff, director of cancer genetic counseling at the Yale School of Medicine, says the claim is misleading because labs like Yale's can conduct only limited testing under the agreement with Myriad."), https://www.usatoday.com/story/opinion/2013/04/14/genes-patent-supreme-court-editorials-debates/2082565/.

In general, governmental funders have moved in the direction of requiring open science and open data, including open-access publication of both results of experiments and of the data underlying those experiments and results. *See, e.g.,* U.S. Dept. of Health and Human Services, NIH Public Access Policy ("To advance science and improve human health, NIH makes the peer-reviewed articles it funds publicly available on PubMed Central. The NIH public access policy requires scientists to submit final peer-reviewed journal manuscripts that arise from NIH funds to PubMed Central immediately upon acceptance for publication."),

https://publicaccess.nih.gov/. In contrast, reductions in government funding of R&D relative to private sector funding have continued to accelerate since the high point of government funding in the 1960s. *See, e.g.,* Congressional Research Service, U.S. Research and Development Funding and Performance: Fact Sheet 2-3 (updated 24 Jan. 2020), ("In current dollars, federal funding for R&D grew from $2.8billion in 1953to $127.2billion in 2018, a compound annual growth rate (CAGR) of 6.1%. In constant dollars, federal R&D grew by a 2.8% CAGR during this period. However between 2011and 2014, federal R&D funding, as measured in current dollars, fell for three consecutive years for the first time since such data has been collected; the total decline in federal funding for these years was $8.7billion (6.8%). In constant dollars, federal R&D declined seven straight years, from 2009 to 2016, by a total 16.8%; a similar drop occurred from1987 to 1994, when federal R&D fell by 16.0%.6In FY2017 and FY2018, federal R&D grew by 1.9% and 2.7% respectively, in constant dollars. Figure 3 shows federal R&D funding by budget function in constant dollars from 1955to 2019…. Business funding of R&D, measured in current dollars, has grown nearly every year since 1953. In current dollars, business-funded R&D grew from $2.2billion in 1953to $404.2billion in 2018, a compound annual growth rate (CAGR) of 8.3%. In constant dollars, business-funded R&D grew by a 5.0% CAGR during this period. In recent years, business-funded R&D has grown at a slower pace. Between 2000and 2018, business R&D grew by a 4.4% CAGR in current dollars, and by a 2.4% CAGR in constant dollars."), https://fas.org/sgp/crs/misc/R44307.pdf. The disinvestment of the government relative to the private sector increases reliance on market mechanisms and IPRs that (as noted above) have failed in regard to pandemic responses. It also increases incentives for private entities to rely upon secrecy rather than seek public funding. Again, these measures impose significant costs on public access to inventions and innovations that are developed, and adversely affect the rights to health and life, as well as education.

4. Affordable access to medicines.

Paragraphs 60-61 of General Comment No. 25 notes that "intellectual property can negatively affect the advancement of science and access to its benefits, in at least in three ways. ... Firstly, intellectual property can sometimes create distortions in the funding of scientific research as private financial support might go only to research projects that are profitable, while funding to address issues that are crucial for economic, social and cultural rights might not be adequate, as these issues do not seem financially attractive for business. ... Second, some intellectual property regulations limit the sharing of information on scientific research for a certain period ... Third, ... intellectual property ... may, in some cases, pose significant obstacles for persons wishing to access the benefits of scientific progress, which may be crucial for the enjoyment of other economic, social and cultural rights, such as the right to health."

There are well-known problems regarding the development and pricing of medicines that reflect these concerns. Reliance on private development, markets, and the intellectual property system has failed to provide affordable access to needed products or to generate products for so-called "neglected diseases". These problems have been highlighted in regard to the pandemic, where prices for many COVID-related products is significantly higher in developing countries than in developed ones. And the pandemic has further revealed the

stresses in the worldwide health care system based on inequality of technological development and wealth, which remains a continuing consequence of the colonial era.

Further, the private system of medicine development often directs large quantities of money to the wrong targets, wasting valuable money on development of and clinical trials for second or third indication medicines of marginal increased effectiveness but which can bring large profits. The social costs, as opportunity costs, are largely invisible, as the public who pays for such medicines cross-subsidizes the waste of financial resources for better health care. Worse yet, the public pays the price in lost health care outcomes and life expectancy, lost productivity, etc. Some of those costs are shifted to the taxpayer through life insurance and other forms of insurance. But reliance on IPRs and on the private markets deprives the public of access to the benefits of science and its applications.

Additional harms result from the failures of many countries to adequately fund R&D for scientific development and health. Such countries seek to free-ride off of the larger share of costs paid by a few countries. Where such funding is paid by developed countries that have a greater capacity to afford the R&D expenditures (which are worldwide public goods) and which have already disproportionately benefitted from technological developments (including as a legacy of colonialism) and thus are in the best position to make use of the funding, such differential funding contributions may be justified. However, even among developed countries there is inequitable sharing of the public R&D burdens, and many developing countries contribute even less than they are capable and less than a "fair share" of the worldwide R&D needs. Accordingly, further attention should be devoted to developing the long-dormant international R&D treaty in the WHO and in other intergovernmental organizations. The failure of governments to adequately invest in scientific development again deprives the public of the benefits of science and applications that would otherwise have been generated, which as opportunity costs may be huge but are inevitably unquantifiable.

5. Scientists compensation, competition, and inducements to restrict information.

As noted, scientists, authors, and others are entitled to the moral and materials interests of their scientific, literary, and artistic creativity. In many cases, however, conditions of employment effectively compel such creative producers to assign their rights for minimal compensation. Although authors' moral rights (in jurisdictions that recognize them) may place a limit on the degree to which such creators can effectively be divested of some of those interests, particularly for minimal compensation, scientists generally lack such moral rights in domestic legislation and are entitled to widely varying compensation for any commercialized inventions that may be patented.

Worse yet, many such creators may be subject to restriction on their ability to produce new works or competing products that would benefit the public through increased diversity of products and lower prices, as a result of non-competition and non-disclosure/non-use agreements in regard to information, data, trade secrets, etc. that they may have developed in the course of their employment. The consequences to the public again are unseen as

opportunity costs, but may be substantial. Cf. Ronald J. Gilson, *The Legal Infrastructure of High Technology Industrial Districts: Silicon Valley, Route 128 and Covenants Not to Compete,* 74 NYU L. REV. 575 (1999) (discussing reduced diffusion of knowledge due to enforcement, and increased diffusion due to non-enforcement, of covenants not to compete). Further governmental intervention in markets and limitations on contractual prohibitions on various kinds of action and know-how diffusion may be needed to assure robust dissemination of such know-how and related data and other activities that would benefit the public, and would better effectuate the public's right to benefit from science and its applications and from other cultural productions.

Conclusion

Although the Rapporteur is to be commended for initiating this Call, the concerns with the rights to science and culture go far beyond toxic substances and their control. It is to be hoped that the Call and the Report will address in more detail the many different facets of these issues. Assuming that they do not, it is to be hoped that additional Reports will seek to address them in detail and to offer suggestions to change our reliance on intellectual property and private markets to generate and distribute equitably the needed benefits of science and of culture.

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