RETHINKING BIOTECHNOLOGY REGULATION IN NIGERIA: THE ROLE OF OPEN SCIENCE AND HUMAN RIGHTS, LESSONS FROM INDIA

Aishatu Eleojo Adaji*

ABSTRACT

This paper analyses the feasibility of adopting open science as an alternative approach to intellectual property rights (IPRs) about biotechnology research and development (R&D) in Nigeria. As the traditional approach to existing intellectual property standards emphasises individual exclusivity and market-driven research and development, particularly in the field of biotechnology, it tends to hamper access to and innovation in biotechnology, particularly in developing countries such as Nigeria. These implicate human rights concerns such as food security and public health. For predicting the prospects and possible legal challenges of establishing an open science-based biotechnology research and innovation system in Nigeria, this paper pays particular attention to what lessons India could offer from adopting open science initiatives. Based on the lessons from India, the paper then explores the adaptation and implementation of an open science policy and legal framework that prioritises human rights concerns such as food security and public health.

Keywords: Biotechnology, Regulation, Nigeria, Open-Science, Human Rights, India

1. Introduction

The norm of sharing is not new, at least among traditional African societies where seeds, traditional agricultural knowledge, and, to some extent, traditional medicinal knowledge are freely shared.[1] Historical narratives have also suggested that the act of sharing knowledge was a norm among research scientists before the commencement of the commercialisation of science in the 1980s.[2] This was linked to the 'scientific revolution' that took place roughly between the 16th and 17th centuries.[3] Scientific research during this period was guided by the notion that the free and open dissemination of scientific findings promotes the progress of science.[4] If ever there was any form of reluctance to share research findings by any researcher,

*LLB, LLM, PhD Honorary Research Fellow, School of Law, University of KwaZulu-Natal, Durban, South Africa, and Lecturer, Department of Public and International Law, Faculty of Law, Osun State University, Osogbo, Nigeria, https://orcid.org/0000-0002-5852-5083, aishatuadaji@gmail.com / eleojo.adaji@uniosun.edu.ng

[1] C Borowiak, 'Farmers' Rights: Intellectual Property Regimes and the Struggle Over Seeds' (2004) 32(4), Politics & Society 511-543; C Oguamanam, 'Open Innovation in Plant Genetic Resources for Food and Agriculture (2013) 13 Chicago-Kent Journal of Intellectual Property 11, 23 - 26.

[2] RS Eisenberg, 'Proprietary Rights and the Norms of Science in Biotechnology Research' (1987) 97 Yale Law Journal 177, 183; AK Rai, 'Regulating Scientific Research: Intellectual Property Rights and the Norms of Science' (1999) 94 Northwestern University Law Review 77, 88.

[3] Y Joly, 'Open Source Approaches in Biotechnology: Utopia Revisited' (2007) 59(2) Me. L. Rev. 385, 391; See also CC George, 'Openness and the Governance of Human Stem Cell Lines: A Conceptual Approach' (PhD Thesis, the University of Edinburgh, 2013) 100.

[4] J Hope, Open Source Biotechnology? (Ph.D. Thesis, Australian National University 2003) 11.

it is believed that such would be driven by academic competition as opposed to commercial competition.[5]

However, the well-known tradition of sharing and disseminating research findings has been challenged by the proliferation of intellectual property rights (IPRs). Built upon the principle of exclusivity, which prioritises private/individual ownership over collective access and use, the current intellectual property (IP) system tends to restrict disclosure and access to scientific research findings and innovations. While in the context of biotechnology, various arguments have been advanced in support of the application of IP standards, there is no strong evidence that it incentivises research and innovation or improves access in developing countries.[6] Rather, it has adverse defects that could hamper the potential of addressing pressing public health and food security challenges, among others, through biotechnology R&D, particularly in developing countries such as Nigeria. These raise human rights concerns, particularly the rights to food and health as well as the right to share in the benefits of scientific advancements.[7]

Reactions to the proliferation of IPRs largely led to the emergence of the free and open source movement in the software industry. Based on unrestricted access to source codes and software innovations, the movement spurred collective use and innovation in the computer software industry.[8] It thereby challenged the traditional IP system, which proceeds from the assumption that exclusive rights are the sine qua non for scientific progress and technological innovation.[9] Motivated by the success of the free and open source software movement, there is an increasing drive to apply the concept of open source or open science to biotechnology R&D and other fields.[10] This has gained more traction since the COVID-19 pandemic.

Given the intersection of human rights and IPRs, particularly in the context of biotechnology, this paper advances an open science approach to the IP framework in the context of biotechnology R&D in Nigeria from a human rights perspective. This prioritises public interests as opposed to the prioritisation of private interests within the traditional IP framework context. It is strongly believed that the open science model can be used to catalyse and accelerate biotechnology R&D in areas that address the specific health, nutrition and other technological needs of Nigeria and other developing countries, as it provides a platform upon which researchers and innovators of diverse expertise can be induced to openly share and

[5] AK Rai, 'Open and Collaborative Research: A New Model for Biomedicine'. In Hahn R.W (Ed), *Intellectual Property Rights in Frontier Industries: Software and Biotechnology* (Federation Press, Australia 2006) 134.

[6] AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents on Public Health and Food Security in Nigeria' (2024) 1(1) Journal of Administration & Law 372 – 397.

[7] The Universal Declaration of Human Rights (UDHR) 1948, arts 25.1 and 27; International Covenant on Economic, Social and Cultural Rights (ICESCR) 1966, arts 11 – 13, 15; AE Adaji, BS Barau, IA Sarumi, 'The Right to Adequate Food and Protection of Agricultural Innovations in Nigeria: A Critical Analysis' (2024) 1(1) Journal of Public and Human Rights Law, 1-8; PK Yu, 'Intellectual property and human rights 2.0' (2018) 53 U. Rich. L. Rev., 1375; P Cullet, 'Human rights and intellectual property protection in the TRIPS era' (2007) 29(2) Human Rights Quarterly, 403-30; LR Helfer, 'Human rights and intellectual property: conflict or coexistence?' (2003) 5 Minn. Intell. Prop. Rev., 47; AR Chapman, 'The human rights implications of intellectual property protection' (2002) 5(4) Journal of International Economic Law, 861-882.

[8] AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents….' (n6) 382 – 383.

[9] ibid.

[10] AE Adaji, LA Abdulrauf, 'Intellectual property issues for open science practices in genomic-related health research and innovation in Africa' (2024) 11(2) Journal of Law and the Biosciences <https://doi.org/10.1093/jlb/lsae026>; AE Adaji, AR Isa, 'The Viability of Patent-Related Flexibilities in Promoting Biotechnology Research and Innovation for Improved Food Security and Public Health in Nigeria' (2024) 7(1) Redeemer's University Nigeria Faculty of Law Journal (RUNLAWJ).

 https://doi.org/10.59568/KIULJ-2025-7-1-02

collaboratively develop intellectual resources for a specific course. In this regard, India's experience in the adoption of open science strategies provides useful insights.

2. IP Regimes for Protection of Biotechnology in Nigeria

Due to its heterogeneity, various forms of IPRs, including patents, plant variety rights, copyrights, and trademarks, among others, apply to the field of biotechnology.[11] The regulation of these IPRs in the context of biotechnology is shaped by various laws or legal standards, established both at the national and international levels. While an indepth analysis of the IP rules fall outside the purview of this paper, it is worth noting that at the national level, the key statutory provisions are as encapsulated in the 2022 Copyrights Act, the 2021 Plant Variety Protection Act, the 1971 Patents and Designs Act and the 1967 Trademarks Act, among others. The Nigerian Copyright Commission, the Nigerian Plant Variety Protection Office (NPVPO), and the Nigerian Industrial Property Office, consisting of the Registries of Trademarks, Patents, and Designs, administer these laws. The laws, to some extent, allow the protection of biotechnology-related intellectual creations and inventions, ranging from genetic databases to literary works and genetic modifications to biotechnological processes.[12]

Also, IP practice in Nigeria is significantly influenced by international agreements or treaties such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS or TRIPS Agreement) 1994 (as amended), the WIPO Copyright Treaty 1996, and the International Convention for the Protection of New Varieties of Plants (UPOV Convention) (1991 Act), among others.[13] This is under Nigeria's membership and/or participation in the World Intellectual Property Organisation (WIPO), World Trade Organisation (WTO) and continental/regional bodies such as the African Union and the International Union for the Protection of New Varieties of Plants (UPOV).[14] Nigeria has, in certain regards, amended its national IP laws to align them with internationally recognised standards.[15] This alignment is critical in fostering an environment that, in theory, encourages both domestic and foreign investment in the biotechnology sector and others.

In practice, however, applying Nigeria's IP regimes in biotechnology faces several challenges, especially as the laws were mostly developed in the pre-biotechnology era and are thus not tailored to address the unique challenges posed by contemporary biotechnology. For instance, issues surrounding the patentability of living organisms, genetic sequences, and biotechnological processes remain contentious.[16] The lack of specialised guidelines or a dedicated regulatory framework for biotechnology can result in uncertainties regarding the scope of protection, especially in cases where traditional knowledge and indigenous resources intersect with modern biotechnological applications.[17]

Also, as Nigeria operates a purely patent registration system where patent applications are merely subjected to formal examination, 'chances are, undeserving biotechnological inventions

[11] AE Adaji, LA Abdulrauf, 'Intellectual property issues for open science practices in genomic-related health….' (n10).
[12] ibid.
[13] A Adaji, 'Patentability of Biotechnology in Nigeria: Reflections on the International Patent Standards' (2024) 6(6) The Journal of Private and Property Law 229 - 239.
[14] ibid.
[15] The Nigerian Copyrights Act 2022.
[16] AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents….' (n6) 376 – 377.
[17] ibid.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

that do not satisfy the patentability criteria of novelty, non-obviousness and industrial applicability are patented'.[18] The weak patent examination in Nigeria impedes the effective handling of biotechnology patents, with patent officers likely to struggle in evaluating biotechnology patents facing nullity claims.[19] In these regards, critics have argued that Nigeria's IP regimes are colonial-oriented or Geneva-centric, designed to satisfy the interests of imperial or Western states or corporations.[20] The rapid growth of biotechnology further exacerbates the issues, leading to inefficient processes, delayed decisions, and a lack of consistency. These factors, among others, would undermine investors' confidence and impede the development of biotechnology in Nigeria.

3. A Critique of the Application of IP to Biotechnology from a Human Rights Perspective

Traditional IP systems have long been defended as essential for fostering innovation and economic growth. However, from a human rights standpoint, these systems are increasingly criticised for prioritising corporate profits and market exclusivity over the broader needs of society.[21] Critics argue that the rigid frameworks governing patents, plant variety protection, copyrights, and trademarks can restrict access to essential medicines, seeds, technology, and cultural resources. [22] This undermines the fundamental human rights to health, food, education, and cultural participation.

One of the central human rights critiques centres on the impact of strict IP protections on public health. Under conventional IP regimes, patents grant exclusive rights to inventors, which often leads to monopolistic pricing of life-saving drugs and vaccines.[23] This has been starkly evident during the HIV/AIDS crisis and, more recently, during the COVID-19 pandemic, where high costs and limited access to patented treatments and vaccines exacerbated health inequalities. The controversy surrounding the IP waiver proposals for COVID-19 vaccines specifically underscores the broader implications of rigid IP systems during global health emergencies. When pharmaceutical companies secure patents that grant them extensive control over vaccine production, developing nations struggle to produce or access affordable doses. Despite overwhelming support from over 100 developing countries for a temporary waiver of IP protections to boost vaccine manufacturing, opposition from wealthy nations and industry stakeholders stalled progress. The delayed response had a ripple effect on public health, delaying widespread immunisation and prolonging the pandemic's socio-economic fallout. Despite the Doha Declaration affirming the rights of WTO members to use compulsory licensing in public health emergencies, many developing countries have struggled to overcome the financial and technical barriers imposed by stringent IP laws, among others.[24]

---

[18] ibid, 337.

[19] Nigerian Patents and Designs Act 1971, sec 9.

[20] I Mgbeoji, 'Bio-Cultural Knowledge and the Challenges of Intellectual Property Rights Regimes for African Development' (2012) 35(2) Dalhousie Law Journal 397, 397 – 423.

[21] T Adebola, 'Examining Plant Variety Protection in Nigeria: Realities, Obligations and Prospects' (2019) 22 The Journal of World Intellectual Property 36.

[22] OO Olusegun and IA Olubiyi, 'Implications of Genetically Modified Crops and Intellectual Property Rights on Agriculture in Developing Countries' (2017) Journal of African Law 1-19; Akintola S.O, 'Intellectual Property Rights and Biomedical Research: Problems and Challenges under the Nigerian Law' (2012) 1(2) NIALS Journal of Intellectual Property 78-99; AE Adaji, BS Barau, IA Sarumi, 'The Right to Adequate Food….' (n7); AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents….' (n6) 374, 379 – 395.

[23] ibid.

[24] AE Adaji, AR Isa, 'The Viability of Patent-Related Flexibilities….' (n10).

 https://doi.org/10.59568/KIULJ-2025-7-1-02

Consequently, the existing system can be seen as failing to uphold the right to health, a core human right recognised under international law.

Another significant critique involves the effect of traditional IP systems on agriculture and food security. The patenting of genetically modified seeds and other agricultural innovations or the protection of new plant varieties has often curtailed farmers' rights to save, exchange, and reuse seeds, a practice integral to traditional farming systems in many developing countries.[25] By these, Nigeria's IP systems, particularly patent and plant variety protection, can increase dependency on multinational companies, potentially leading to the high pricing of seeds and other propagating material beyond the reach of smallholder farmers and threatening local genetic diversity.[26] This not only impacts the right to food but also jeopardises the traditional agricultural knowledge systems in Nigeria.[27]

Generally, the globalised IP standards have often been criticised for failing to accommodate traditional knowledge, particularly those associated with the conservation and sustainable use of diverse genetic resources for food and medicine.[28] The *Neem* patents, the case of *Hoodia*, and the *Enola* beans patent are among the many cases where IP claims are made on biotechnology innovations largely based on traditional medical or agricultural knowledge.[29] These cases of traditional knowledge misappropriation or biopiracy, in effect, erode the cultural practices of indigenous communities and their ability to provide food and medicine for themselves while depriving them of economic benefits.[30]

In essence, the current globalised IP system can be viewed as a double-edged sword from a human rights perspective. While it has the potential to incentivise research and development in the context of biotechnology, it can also impede access to critical innovations and various forms of intellectual output. These have propelled the calls for reforms and advocacy for more flexible and human rights-oriented IP regimes. This is to strike a balance between rewarding and incentivising innovation and creativity on the one hand and ensuring public interests through equitable access to the benefits of biotechnology on the other hand. In this regard, various legal doctrines and alternative possibilities have been proposed, including the enhancement of TRIPS flexibilities, integration of access and benefit-sharing principles, and adoption of collaborative mechanisms such as open science.[31] The remaining part of this paper thoroughly explores the open science concept with specific regard to India, towards proffering a human rights-oriented IP framework for biotechnology R&D in Nigeria.

4. Open science in biotechnology

[25] T Adebola, 'Examining Plant Variety Protection in Nigeria….' (n21); AE Adaji, BS Barau, IA Sarumi, 'The Right to Adequate Food….' (n7).

[26] Ibid; OO Olusegun and IA Olubiyi, 'Implications of Genetically Modified Crops….' (n22) 15.

[27] ibid; AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents….' (n6) 394 – 395.

[28] ibid.

[29] For more detailed discussions on the above highlighted cases and others see, Dewani N.D and Gurtu A (Eds), *Intellectual Property Rights and the Protection of Traditional Knowledge* (IGI Global, 2020); Ageh P.A and Lall N, 'Biopiracy of Plant Resources and Sustainable Traditional Knowledge System in Africa' (2019) 8 Global Journal of Comparative Law 162, 178.

[30] AE Adaji, BS Barau, IA Sarumi, 'The Right to Adequate Food….' (n7); AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents….' (n6) 394 – 395.

[31] AE Adaji, AR Isa, 'The Viability of Patent-Related Flexibilities….' (n10).

 https://doi.org/10.59568/KIULJ-2025-7-1-02

In recent years, food crises and major disease outbreaks such as Ebola and COVID-19, are driving governments, international organisations such as the World Health Organisation (WHO) and the United Nations Educational, Scientific and Cultural Organization (UNESCO), scientists, legal experts and other stakeholders to seek alternative or complementary approaches to IPRs, particular in the context of biotechnology, genomic and pharmaceutical research.[32] This is to incentivise need-based research and the development of affordable technologies for people in developing countries like Nigeria, leveraging the expertise of diverse researchers and open sharing of knowledge, research results, and IP assets, among others.[33]

The UNESCO Recommendation on Open Science 2021 defines open science as:

> an inclusive construct that combines various movements and practices aiming to make multilingual scientific knowledge openly available, accessible and reusable for everyone, to increase scientific collaborations and sharing of information for the benefits of science and society, and to open the processes of scientific knowledge creation, evaluation and communication to societal actors beyond the traditional scientific community.

In other words, it encompasses diverse open movements, including open access to publications, open data, free and open-source software, open collaboration, open peer review, and open educational resources.[34] It also comprises 'all scientific disciplines and aspects of scholarly practices, including basic and applied sciences, natural and social sciences and the humanities'.[35]

Open science in the context of biotechnology emphasises the sharing and unrestricted access, use, and further improvements or modifications of research findings or data, scientific publications, software and source codes, and research methodologies, among others.[36] In contrast to proprietary systems where access, use, sharing, modification or adaption of biotechnology innovation or other intellectual creations are fenced by IPR, such as patents, plant variety rights and copyrights, plant variety rights, patents and trade secrets guard innovations and other intellectual creations, open science initiatives promote sharing and unrestricted access among researchers and institutions, engendering collaborative research.

---

[32] The 2020 tripartite report of the WHO, WIPO and WTO particularly echoes the various calls for new and alternative approaches to traditional intellectual property rights, including open science. The WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* (2nd Edition, WHO, WIPO and WTO, Geneva 2020) 151 – 165; See also WTO, 'The TRIPS Agreement and COVID-19' (Information Note Prepared by the Secretariat, 15 October 2020) <https://wto.org/English/tratop_e/covid19_e/trips_report_e.pdf> accessed on 30 January 2025; The UNSG HLP on Access to Medicines, 'Promoting Innovation and Access to Health Technologies' (Report of the UNSG HLP on Access to Medicines, Geneva 2016) 29 – 32; WHO, 'Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination' (Report of the consultative expert working group on research and development: financing and coordination 2012) 48 – 63; AE Adaji, LA Abdulrauf, 'Intellectual property issues for open science practices in genomic-related health….' (n10).

[33] ibid.

[34] AE Adaji, LA Abdulrauf, 'Intellectual property issues for open science practices in genomic-related health….' (n10).

[35] UNESCO Recommendation on Open Science 2021, para II.6.

[36] UNESCO Recommendation on Open Science 2021; WTO, 'The TRIPS Agreement and COVID-19' (n32) 3 – 5.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

This is because open science is founded on the core values of diversity and inclusiveness, collective benefit, equity and fairness, and quality and integrity.[37]

These core values of open science, which are in themselves rights-based, open science beyond the traditional scientific society, 'broadening the principles of openness to the whole cycle of scientific research'.[38] They are particularly impactful in a field such as biotechnology, where research and innovation are cumulative, sequential, and complementary, requiring rapid dissemination and exchange of research findings and innovation. The openness accelerates innovation by reducing duplication, promoting cross-disciplinary collaborations, and lowering costs associated with research and development. In the context of health, for example, open science has facilitated rapid responses to emerging crises, as seen during the COVID-19 pandemic.[39] Since open science democratises access to scientific knowledge, it enables researchers from resource-limited settings to contribute to and benefit from global advancements.

A significant critique of conventional IP regimes is that they can exacerbate inequalities by limiting access to essential technologies, seeds, and medicines. Open science, by promoting science as a global public good, seeks to ensure that innovations benefit society as a whole rather than a privileged few.[40] In the context of biotechnology, this means making critical advancements such as vaccines, diagnostic tools, and agricultural innovations available to all, particularly in low- and middle-income countries. By aligning with human rights and sustainable development goals, open science principles in biotechnology can bridge the gap between innovation and human well-being, fostering a more inclusive and just scientific ecosystem.

Notable examples include the adoption of the open science approach during the COVID-19 pandemic.[41] Researchers around the world rapidly shared genomic data, protocols, and preprints, leading to unprecedented speed in vaccine development and diagnostic tool creation.[42] Initiatives such as the COVID-19 Open Research Dataset (CORD-19) exemplify how open access to research materials can facilitate cross-disciplinary collaboration, driving innovation and enabling faster public health responses.[43] The open science platforms allow for the creation of community-driven projects that harness the collective expertise of global networks, breaking down silos that often hinder progress in high-stakes research areas.

International collaborations, such as the Open Source Malaria project, demonstrate the potential of open science to tackle complex diseases.[44] By sharing experimental data and compound libraries openly, researchers collectively identify promising therapeutic candidates while reducing duplication of efforts and resource wastage. Such an open, collaborative platform is especially crucial for addressing neglected tropical diseases and conditions besetting developing countries, including Nigeria. The market-driven nature of existing IP

[37] UNESCO Recommendation on Open Science 2021, para III.
[38] ibid.
[39] WTO, 'The TRIPS Agreement and COVID-19' (n32) 3 – 5.
[40] UNESCO Recommendation on Open Science 2021, para III.13.
[41] WTO, 'The TRIPS Agreement and COVID-19' (n32) 3 – 5.
[42] ibid.
[43] 'The COVID-19 Open Research Dataset (CORD-19)' <https://github.com/allenai/cord19> accessed 05 February 2025.
[44] 'Open Source Malaria: Looking for New Medicines' <https://opensourcemalaria.github.io/NewSite/> accessed 05 February 2025.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

standards does not incentivise biotechnology R&D due to the low purchasing power of those largely affected.[45]

However, it is worth noting that open science is not without challenges. Issues such as funding and the need for robust governance frameworks remain critical. Without the financial incentives provided by proprietary IP, sustaining long-term research initiatives may require alternative funding models and incentives, such as public-private partnerships or government grants. Policymakers and industry stakeholders must work together to create environments that balance openness with the need to reward innovation. Developing legal and regulatory frameworks that support open science while protecting the interests of creators and the public will be key to fostering a sustainable, equitable global biotechnology ecosystem. The following section analyses how India in embracing open science principles strive to balance the incentives for innovation with the collective right to access and benefit from scientific progress.

5. India's Open Science Framework

India's journey in reforming its IP system is marked by a series of landmark policy changes that have sought to balance the need for innovation with broader public welfare. Over the past few decades, India has restructured its IP laws in response to international obligations, including the TRIPS Agreement, while ensuring that the domestic system remains sensitive to public health, food security, affordable access to technology, and socio-economic development.[46] Concurrently, India has emerged as a global pioneer in open science initiatives, which serve as complementary models to traditional IP protection by promoting transparency, collaboration, and equitable access to knowledge.

In sectors such as software development and biotechnology, open source and open science initiatives have played a pivotal role in democratising access to knowledge and fostering collaborative research. The Policy on Adoption of Open-Source Software for the Government of India 2015 and Framework for Adoption of Open-Source Software in e-Governance Systems 2015, among others, encourage the formal adoption and development of Open-Source Software (OSS) in public institutions, reducing dependency on expensive proprietary software and stimulating local innovation.[47] This policy not only cuts costs but also builds technical capacity among developers and public sector agencies. In the realm of biotechnology, several research institutions and startups have adopted open science principles by sharing genomic data, research protocols, and even software tools openly. These, as exemplified by the often-cited Indian Open Source Drug Discovery (OSDD) Project, are to ensure that the constitutional

[45] AE Adaji and RG Okplogidi, 'Critical Analysis of the Implications of Biotechnology Patents….' (n6) 392 – 393.

[46] US Racherla, 'Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry'. In Liu K.C and Racherla U (eds), *Innovation, Economic Development, and Intellectual Property in India and China*. (Springer, Singapore, 2019) 271-298; JO Dountio, 'The Indian Protection and Utilisation of Public Funded Intellectual Property Bill, 2008: Does It Secure Access to Medicines?', p.146; AE Adaji, 'TRIPS Compliance and Biotechnology Patenting in Africa: Lessons from India' (2024) 11(2) Journal of Commercial and Property Law 142-53.

[47] The Policy on Adoption of Open Source Software for Government of India 2015 <https://meity.gov.in/writereaddata/files/policy_on_adoption_of_oss.pdf> accessed 05 February 2025; Framework for Adoption of Open Source Software in e-Governance Systems 2015 <http://egovstandards.gov.in/sites/default/files/Framework%20for%20Adoption%20of%20Open%20Source%20Software%20in%20e-Governance%20Systems.pdf> accessed 05 February 2025.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

rights of the people of India, including the right to health, are not compromised by the highly defective global IP system.

The Indian Open Source Drug Discovery initiative launched in 2008 is in recognition of the lack of substantial investment and research in diseases affecting mainly developing countries, such as tuberculosis, a situation which, as highlighted before, is due to the inability of patients to pay for costly drugs.[48] It is also in recognition of the tendency of the conventional IP system to foster secrecy and hamper open participation among experts from diverse fields across the world who could leverage each other's expertise to stimulate the R&D process.[49] Thus, led by the Council of Scientific and Industrial Research (CSIR) of India, the primary objective of the OSDD is to ensure affordable healthcare for developing countries.[50]

To achieve its purpose, the OSDD is designed as a global and decentralised initiative that provides a platform for collaboration and open sharing among researchers in academia, research laboratories, and industry, doctors, technocrats, software professionals, students, and many others with expertise from diverse fields across the world. It is believed that the collaborative and open approach, as in the case of open source software, could expedite the drug discovery and development process while minimizing cost.[51] Consequently, adopting an open science model in drug discovery would ensure the availability of drugs at affordable prices, especially as it is envisaged that the inventions discovered will be made available in a non-exclusive manner for multiple companies to participate in the manufacturing and distribution of the end drugs. At the centre of the OSDD is SysBorg (Systems Biology of the Organism), the web portal that acts as the open source software's sourceforge.net. This provides the virtual laboratory framework within which the participants, comprising more than 7900 from across the globe, engage in scientific discussions, share resources including scientific data and ideas, articles, software applications, lab notes, results of experiments and patented inventions, as well as seek collaborations, funding or even organise and manage research projects.[52] It ensures that all research results and data are uploaded in real-time, displacing the traditional practices whereby results and data are safeguarded till publication.[53]

Regarding the ownership of IPRs, the resources generated belong collectively to the community of participants.[54] But to ensure that available resources are not appropriated by free-riders, the proprietary rights are obtained and held in trust by the OSDD through the CSIR. While the proprietary rights are freely licensed under the OSDD license in furtherance of the objective of the initiative, the OSDD reserves the power to take necessary legal actions,

---

[48] A Bhardwaj et al, 'Open Source Drug Discovery: A New Paradigm of Collaborative Research in Tuberculosis Drug Development' (2011) 91(5) Tuberculosis, 479, 479-486.

[49] ibid; A Bhardwaj et al, 'Open Source Drug Discovery: A Global Collaborative Drug Discovery Model for Tuberculosis' (2011) 77 (1–2) Science and Culture, 22; CSIR-India, 'Frequently Asked Questions'. <http://www.osdd.net/about-us/faq-s> accessed 05 February 2025.

[50] ibid; Z Thomas, 'Open Source Drug Discovery: An Open Collaborative Drug Discovery Model for Tuberculosis' (A Proposal Submitted before WHO CEWG on Research and Developing Financing) 1-3, 7.

[51] Z Thomas, 'Open Source Drug Discovery….' (n49) 2.

[52] CSIR-India, 'Virtual Collaboration: SysBorg 2.0 (Systems Biology of Mycobacterium and Plasmodium)' <http://osdd.net/about-us/how-osdd-works/sysborg-2-0> accessed on 30 September 2021.

[53] ibid; Thomas Z, 'Open Source Drug Discovery: An Open Collaborative Drug Discovery Model for Tuberculosis', p.5.

[54] CSIR-India, 'OSDD Policies' <http://osdd.net/about-us/osdd-policies> accessed on 30 September 2021; See also paragraph 3 of the Indian Open Source Drug Discovery Terms and Conditions.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

especially against free riders.[55] Interestingly, the OSDD also incorporates the 'grant back' principle so that whoever accesses the community's resources is obligated to give back to the community all improvements or developments, whether or not IP protection has been obtained, under a worldwide royalty-free nonexclusive license. This is to foster an open and collaborative spirit, ensuring further improvements or developments by anybody in line with the aim of the initiative.

Another significant feature of the OSDD is the micro-attribution system embedded in the SysBorg through which each contribution of every participant is time and login stamped.[56] This ensures that the inputs and contributions made by participants to projects, whether in the form of discussions, blog entries or ideas, experimental results, or data, and many other resources, are tracked and properly attributed. By implication, in tracking the contributions, the micro-attribution system protects each participant's contribution against third-party claims or misappropriation. In addition, the OSDD provides rewards and prizes based on the micro-attribution system, which assigns credit points to contributions. The credit points to each participant's contributions, which accrue over time, can be converted to awards, whether monetary or non-monetary.

Along with the OSDD, the government and various institutions in India, including research institutions and universities, are also taking steps in line with the global open movement. For instance, in 2020, the Indian government published the draft Science, Technology and Innovation Policy (STIP-2020), which contained elaborate provisions for the establishment of an open science framework for India.[57] Under the open science framework, access to scientific data, resources, information, and knowledge shall be granted to everyone in the country on an equal partnership basis. Particularly, all data used in and generated from publicly-funded research is to be available to everyone under FAIR (findable, accessible, interoperable, and reusable) terms. India's National Intellectual Property Rights Policy (NIPRP) 2016 also speaks about encouraging research and development in India through the open science approach.[58]

Furthermore, in 2014, the Indian Department of Science and Technology (DST) and Department of Biotechnology (DBT), both of India's Ministry of Science and Technology, jointly adopted an open access policy regarding research fully or partially funded by them or carried out using infrastructure built with their support.[59] Similarly, the Indian government pursues an open data policy under the 'National Data Sharing and Accessibility Policy' (NSDAP), issued in 2012 through the Department of Science and Technology.[60] The policy is being implemented by all the MDAs of the Indian government, in light of which its Department

---

[55] ibid.

[56] Bhardwaj A et al, 'Open Source Drug Discovery: A New Paradigm of Collaborative Research in Tuberculosis Drug Development', pp.480-481; Bhardwaj A et al, 'Open Source Drug Discovery: A Global Collaborative Drug Discovery Model for Tuberculosis', pp.22-23; Thomas Z, 'Open Source Drug Discovery: An Open Collaborative Drug Discovery Model for Tuberculosis', pp.2, 5, 7; CSIR-India, 'Frequently Asked Questions'.

[57] Science, Technology and Innovation Policy (STIP-2020) <https://www.psa.gov.in/psa-prod/psa_custom_files/STIP_Doc_1.4_Dec2020.pdf> accessed on 21 February 2025.

[58] paragraphs 2.10 and 5.12 of the Indian Intellectual Property Rights Policy, 2016.

[59] See 'DBT and DST Open Access Policy: Policy on open access to DBT and DST funded research', 2014 <https://dst.gov.in/sites/default/files/APPROVED%20OPEN%20ACCESS%20POLICYDBT%26DST%2812.12.2014%29_1.pdf> accessed on 30 September 2021.

[60] National Data Sharing and Accessibility Policy (NSDAP), 2012 <https://dst.gov.in/sites/default/files/nsdi_gazette_0.pdf> accessed on 30 September 2021.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

of Biotechnology formulated the 'Biological Data Storage, Access and Sharing Policy of India' in 2019 to guide public-funded research leading to the generation of biological data.[61]

Interestingly, the Indian government is also exploring the potentials of the Traditional Knowledge Digital Library in facilitating the open science approach to drug R&D.[62] Other notable initiatives in India include the 'ShodhGanga: Reservoir of Indian Theses' which makes theses written by students of Indian universities freely accessible on the Internet, and the Delhi Declaration on Open Access of 2018, which encourages opening up access to research outputs for the public good in India. The Directory of Open Access Journals (DOAJ) lists a considerable number of scholarly journals being published in open access by government departments, academies, professional bodies, and other institutions in India.

6. India's Open Science Paradigm as Human Right-Based

India's IP system, like Nigeria's, is influenced by Western ideas.[63] However, an important and distinguishing fact is that there is a greater awareness in India of the potentially devastating impact of IPRs on public health and food security, as reflected in the historical development of its IP system.[64] Therefore, in enacting, interpreting, and implementing IP laws, the government of India avails itself of all possible legal mechanisms, including the TRIPS flexibilities and the Doha Declaration. More significantly, the Indian legislature and courts have often considered India's constitutional provisions safeguarding the rights of the people.[65]

Even so, the reintroduction of product patents and the continuous pressure on India to commit to IP standards beyond the TRIPS Agreement has become a source of increasing concern not only for India but also for other developing countries.[66] This is because they threaten to retard the industrial progress of the country and undermine the country's important role in promoting access to and supplying affordable drugs and technologies to the developing world. Hence, after the TRIPS-driven amendments, it did not take long for the government of India to establish an open source platform for drug discovery and development while supporting other open science initiatives, as demonstrated above.

In other words, the various open science initiatives in India reflect the country's concern over the impending challenges that the changes in the IP system could again pose to public health, nutrition, and welfare, given its experience in the past. Keeping in view India's emphasis on human rights protection in the adaption, interpretation and implementation of IP laws, the open

---

[61] See Biological Data Storage, Access and Sharing Policy of India 2019 <http://dbtindia.gov.in/slider/biological-data-storage-access-and-sharing-policy-india> accessed on 30 September 2021.

[62] WIPO, 'International Conference Concludes TKDL Can Prevent Misappropriation and Fuel Innovation'. Press Release, (PR/2011/68 24 March 2011) <https://www.wipo.int/pressroom/en/articles/2011/article_0009.html> accessed on 30 September 2021.

[63] US Racherla, 'Historical Evolution of India's Patent Regime and Its Impact on Innovation in the Indian Pharmaceutical Industry'. In Liu K.C and Racherla U (eds), Innovation, Economic Development, and Intellectual Property in India and China. (Springer, Singapore, 2019) 271-298; S Chaudhuri, 'Are Medicine Prices High and Unaffordable After TRIPS? Evidence from Pharmaceutical Industry in India' (Commentary on India's Economy and Society Series – 10, Centre for Development Studies, India 2019) <http://cds.edu/wp-content/uploads/2020/01/CommentarySeirs10_Sudip.pdf> accessed on 26 February 2025; AE Adaji, 'TRIPS Compliance….' (n45).

[64] ibid.

[65] ibid.

[66] S Chaudhuri, 'Are Medicine Prices High….' (n64); AE Adaji, 'TRIPS Compliance….' (n45).

 https://doi.org/10.59568/KIULJ-2025-7-1-02

science paradigm provides the appropriate framework and principles through which the country promotes scientific or technological R&D while meeting its human rights obligations, including the right to life, health and food of its people. The OSDD is thus based on the tenet that 'a drug at an affordable cost is the right of all'.[67] Particularly, the project initiator, Professor Samir K. Brahmachari, then Director General of the Indian Council of Scientific and Industrial Research, emphasised as follows:

> I believe that affordable healthcare is a right for all. But pragmatically speaking, when it comes to health, we need to have a balanced view between health as a right and health as a business. Therefore, it is the responsibility of public-funded institutions to participate in this area in an open, collaborative mode.[68]

Arguably, this serves as a unique approach to open science from which Nigeria can draw insights. It also underscores the significant place of the public sector in the technological innovation system, exemplified by India's CSIR and Department of Biotechnology, among others. In this vein, given the persisting health and food challenges in Nigeria despite the existing IP laws, the application of the open science approach in the biotechnology context is argued from a human rights standpoint where the various academic and research institutions in the Nigerian public sector thus have significant roles to play. While the OSDD focuses on health, the same conceptual underpinning can be transplanted to other areas of biotechnology R&D, as reflected in the subsequent open policies of the Indian government.

In light of the above, the remaining part of this paper analyses the feasibility of an open approach to IPRs in the context of biotechnology R&D in Nigeria from a human rights perspective.

7. Lessons From India for the Development of an Open-Source Biotechnology Framework in Nigeria

The various efforts by the Indian government to adapt the globalised IP standards to suit its domestic interests, particularly with regards to health and food security is very important given India's key role in the negotiation of international IP standards for and supply of affordable drugs and other technologies, both patented and generic to developing countries including Nigeria. Specifically, Nigeria and India face similar challenges in biotechnology R&D in terms of the historic imposition of IP systems by their British colonialists and current efforts by the developed countries, including the United States, to make both countries adopt stronger IP regimes through economic and trade sanctions. Bearing this in mind, it is important to ask whether there are insights for Nigeria from India's pragmatic response to the challenges of IPRs through the open science model.

---

[67] Z Thomas, 'Open Source Drug Discovery: An Open Collaborative Drug Discovery Model for Tuberculosis' (A Proposal Submitted before World Health Organisation Expert Working Group on Research and Developing Financing) 2; SK Brahmachari, 'The Open Source Drug Discovery Project: Need for Global Collaboration'. (Paper Presented at the 9th European Congress on Tropical Medicine and International Health, Basel 07 September 2015) <https://www.dndi.org/images/stories/events2015/ectmih/S.Brahmachari_DNDi_ECTMIH_2015.pdf> accessed on 30 January 2025.

[68] SK Brahmachari, 'Message from the Chief Mentor' <http://www.osdd.net/message-from-the-chief-mentor> accessed on 30 January 2025.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

The following discussions emphasise selected aspects that are of particular relevance in designing an open science framework for biotechnology R&D in Nigeria.

8. The Need for A Human Rights-Based Open Biotechnology Framework in Nigeria

As highlighted earlier, both fields of biotechnology and IPRs have, over the years, generated significant debates in terms of human rights. In addition to the human rights concerns already discussed above, it is worth noting that about aspects of biotechnology, such as cloning and stem cell research, the protection of human dignity has been at the centre of ongoing debates. The persisting debates relating to human rights principles are shaping both international and national legal instruments and guidelines in both fields of biotechnology and IPRs, such as the Doha Declaration on the TRIPS Agreement and Public Health of 2001 and the Universal Declaration on Bioethics and Human Rights of 2005.

In light of the foregoing, it is evident that human rights values are important elements which must be taken into consideration in the application of IPRs to biotechnology in order to achieve a balance between private and public interests in Nigeria. This paper argues that open science offers a viable framework within which to achieve this balance, while fostering innovation and access. India has taken the lead to explore this potential, as pointed out in this paper. It is on these bases that this paper advances the adaptation of an open science framework for biotechnology R&D in Nigeria from a human rights point of view.

Pushing the above arguments further, it is important to state that human rights commitments create legally binding obligations on State parties, at the core of which is the 'obligation to fulfil'. The obligation to fulfil means States must take positive steps, adopting appropriate measures and legislations that would *inter alia* 'facilitate, provide and promote', availability and accessibility of relevant technologies and information in fulfilment of human rights, including the right to health and the right to food. Specifically, in the context of right to health, a State's obligation to fulfil requires it to *inter alia* put in place interventions that promote the development of and access to medicine. Regarding the right to food, State Parties must be proactive in strengthening people's access to and use of resources and means of ensuring their livelihoods, including food security.

In all of the above respects, the current IP framework has been proven to be obstructive, as shown in this paper and existing literature. Thus, by extension, the government is in breach of its human rights obligations. But there is a strong presumption that the potential of open science standards to promote biotechnology research, innovation and access provides the context within which the Nigerian government can take deliberate, concrete and targeted steps towards addressing specific public health and food security issues while simultaneously fulfilling existing international obligations both in terms of human rights and IPRs. Furthermore, it is submitted that the open and inclusive nature of the open science is consistent with the right to share in the benefits of scientific advancements enshrined in Article 27(1) of the UDHR, 1948 and Article 15(1) of the ICESCR, 1966.

The practical implication of designing a human right-based open biotechnology model is that it imposes a legally binding obligation on the government to engage in R&D, particularly in areas where proprietary rights tend to undermine human rights interests, and greater emphasis will be on the promotion of public interest in biotechnology R&D. In other words, by integrating a human right element in the alternative framework provided by open science in the context of biotechnology, public interests with particular emphasis on the rights to health and

 https://doi.org/10.59568/KIULJ-2025-7-1-02

food, take precedence over private property rights while the traditional IP system favouring private interests continues to exist.

9. The Role of the Nigerian Government

Recognising the need for state intervention due to the failures and challenges of the current proprietary approach obtainable under the global IP system, the Indian government, through its various agencies such as the Department of Biotechnology and CSIR, adopted alternative, non-proprietary, open science-based initiatives and policies such as the Indian Open Source Drug Discovery initiative. The point here is, as in the case of India, ensuring the realisation of the human rights objectives under an open collaborative framework for biotechnology development in Nigeria requires a system modelled on and led by the coordinated research efforts and knowledge creation of the government. Particularly, the numerous publicly-funded institutions engaging in biotechnology R&D in Nigeria, including the National Biotechnology Development Agency (NABDA) and the Sheda Science and Technology Complex (SHESTCO) can be mandated to carry out their research in an open collaborative mode.

Inadequate funding and infrastructures in terms of the laboratory equipment, power supply, internet and consumables, among others, needed for biotechnology R&D, continue to constitute significant constraints in Nigeria. Olasoju and others, in examining the prospects and challenges in biotechnology in Nigeria, particularly identified inadequacy in human resources and expertise as among the major challenges in Nigeria.[69] They posit that, as an intensive research area, biotechnology needs highly skilled human resources. Unfortunately, the studies suggest a decline in this regard in the tertiary and research institutions in Nigeria, partly due to brain drain as researchers seek greener pastures, as well as inadequate funding of education and specialist training on the part of the government.[70] The studies also indicate that biotechnology research in Nigeria is often carried out in isolation and is not collaborative.[71] This, as noted, impacts on funding and harmonisation of biotechnology research, as meagre resources are wasted on overlapping research and other correlated activities.[72]

No doubt, there is a dire need for the Nigerian government to improve on its commitments in terms of funding and infrastructure, among others. This is in order to not only promote biotechnology R&D but also to make the various biotechnology-related disciplines, including agriculture, an increasingly attractive career choice to the Nigerian populace. Furthermore, being the principal body charged with the development of biotechnology in Nigeria, it is submitted that the NABDA should be positioned to play a pivotal role in identifying national priorities in terms of health and food security, as well as in initiating, coordinating, supporting and sustaining open and collaborative biotechnology R&D among other government agencies, research institutions and academia. Notwithstanding the emphasis on state actors, the government must also form alliances with other stakeholders in both the formal and informal

[69] SA Olasoju et al, 'Problems and Prospects of Agricultural Biotechnology in Nigeria's Developing Economy' (2018) 12(11) International Journal of Agricultural and Biosystems Engineering 418, 421; TA Adisa and AT Isaac, 'Institutional Challenges to the Development of Sustainable Agricultural Biotechnology in Nigerian National Agricultural Research System (NARS)' (2016) 1(1) International Journal of Science and Applied Research 33, 36.

[70] ibid.

[71] TA Adisa and AT Isaac, 'Institutional Challenges ….' (n75) 34; TJ Ivase et al, 'Current Status and Challenges of Agricultural Biotechnology in Nigeria: A Concise Review' (2019) 6(9) Journal of Multidisciplinary Engineering Science and Technology 10656, 10660.

[72] TJ Ivase et al, 'Current Status and Challenges of Agricultural Biotechnology….' (n77) 10660.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

sectors, at the national and international levels. These would include holders and users of traditional knowledge, such as local farmers and indigenous people, hospitals and biotechnology-based business entities or companies in the pharmaceutical and agricultural industries, especially about trials and product development.

As in the case of India, new technologies resulting from the open collaborative research should be made available under the generic industry business model, so that anyone could manufacture and distribute the end products. In this context, the IPRs, if any, play inclusive roles as opposed to excluding or restricting users. Significantly, the unrestricted access and distribution of resources within the open science framework could engender healthy competition and thereby drive down the prices of the derived goods and services while ensuring availability. The affordability and availability of the relevant technology is also ensured by reason of the fact that the open development of technology essentially delinks research costs from product prices.

Overall, this paper contends that the open science framework could address some of the issues identified above, particularly about resources. This is because the collaboration within the research community facilitates unrestricted access to biological data, research tools and other materials among collaborators. It also minimises waste of resources, including funding, as it prevents the duplication of research. Minimising the waste of resources could indirectly improve funding for research in Nigeria, especially as existing resources are shared.

10. India's Micro-Attribution System, Incentivising and Delinking Mechanisms

Recognising the need to address IP issues and incentivise participation in an open collaborative manner, the OSDD establishes the attribution and reward system discussed above. In terms of IPRs, the micro-attribution system ensures that a person's contribution is not claimed or misappropriated by another person and thereby encourages the sharing and exchange of ideas, research data or results, among others. This is important as it could be used to allay the fears of potential contributors that their ideas or research works could be hijacked and ownership claimed by others when shared openly. It can be safe to argue that those who look to have their works as a reference point stand to benefit from an open science system and become well-known among their peers based on the extent of contributions attributable to them. This will also encourage participation within the open collaborative framework. Beyond the protection of intellectual contributions, rewards and prizes are embedded in the micro-attribution system, as discussed above.

All of the above accord with the views that additional strategies could be incorporated into the open source or open access framework to incentivise or reward sharing and participation in open collaborative research. Various mechanisms have been proposed to provide alternative and non-proprietary incentives, including prize-type (milestone prizes and end prizes), tax breaks, grants and contributions in-kind. [73] These incentive mechanisms, which can be broadly categorised into push and pull incentive mechanisms, are complementary.[74] Push mechanisms such as grants and contributions in-kind are meant to kick-start a project, whereas pull mechanisms such as prizes are meant to reward efforts, especially 'after an objective or

[73] See for instance 'BOAI15 Survey Results' (Budapest Open Access Initiative, 2018) 2 <https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=1077&context=scholcom> accessed on 23 February 2025.

[74] For an explanation of various push and pull incentive mechanisms, see the UNSG HLP on Access to Medicines, 'Promoting Innovation and Access….' (n32) 29.

 https://doi.org/10.59568/KIULJ-2025-7-1-02

milestone has been reached'.[75] Beyond inducing or rewarding sharing and participation in open science-based R&D, they are also designed to delink R&D costs from the prices of the final products.[76] Concerning Nigeria, financial grants may be considered a key incentivising mechanism. Other existing incentivising mechanisms that could be explored within the open science model include national honours or recognition and recommendations for promotion, among others.

11. Conclusion

India has, over the years, leveraged on TRIPs flexibilities and adapted IP standards to suit its national interest and level of development. However, through the threat of economic sanctions and bilateral agreements, developed countries such as the US have sought to impose more stringent IP standards on India against the country's commitments to public interest. Recognising that the increasingly stringent global IP framework does not ensure the health and food needs of the people, India chose to establish various open science-based initiatives, including the OSDD. In analysing India's open science-based initiatives, the key features were highlighted for the purpose of drawing useful insights for the establishment of an open science-based framework for biotechnology R&D in Nigeria. Particularly, this paper proposed a human rights-based open collaborative framework for biotechnology R&D in Nigeria. This is to be modelled on and led by coordinated research efforts and knowledge creation by researchers and academic scientists in public research institutions and universities in Nigeria. Within this context, the paper also envisages the incorporation of reward and incentive mechanisms into the architecture of the proposed framework.

In all, this paper aligns with the argument that, as opposed to the traditional proprietary and market-driven approach to biotechnology R&D being propelled by the current global IP standards, the open science approach can facilitate innovation in and access to biotechnology in Nigeria and other developing countries. The public health and food security challenges confronting Nigeria and many other developing countries could be addressed through open collaborative R&D in biotechnology. However, it requires a greater commitment from the government.

[75] ibid.

[76] ibid; See also WHO, WIPO and WTO, *Promoting Access to Medical Technologies and Innovation*…. (n32) 155 – 163.

 https://doi.org/10.59568/KIULJ-2025-7-1-02