Bioethics and Biotechnology Related Intellectual Property and Intellectual Property Rights in Zimbabwe: Issues and Opportunities for Development

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Abstract

This paper discusses the bioethics of intellectual property (IP) and intellectual property rights (IPR) applicable to biotechnology-based IP. It outlines some of the laws that are related to IPR in Zimbabwe and globally. The paper additionally highlights gaps, opportunities and concerns with the laws. Finally, the paper highlights some initiatives already underway in Zimbabwe targeted at promoting entrepreneurship, commercialization and industrialization while proposing strategies that can be used to further promote the generation and granting of biotechnology-related IP and IPR in Zimbabwe.

Keywords: Patents, Plant Breeders Rights, IPR laws, Traditional Knowledge, Strategies

Introduction

Intellectual property (IP) and intellectual property rights (IPR) are of great importance in the economic and social development of countries (Kumar, 2021; Belderbos *et al.*, 2021). IPRs help secure information or ideas from theft or competitors' encroachment (Zafar, 2020). Based on reward theory, those who invest their time to undertake risky and costly investments to generate new ideas and technologies should be given incentives in the form of IPRs (Sharma and Kumar, 2018, Hilty *et al.*, 2020; Hamm, 2020). These rights stretch to the

protection of the moral and material interests resulting from any IP generated (Lennhammer, 2020). Such protection has been found useful and a prerequisite for better management and commercialization of IP (Zafar, 2020). IPR gives inventors temporary exclusivity, but the community benefits in the long run (Lennhammer, 2020; Rafina *et al.*, 2019). IPRs create a positive environment for innovation and creativity thereby promoting economic growth (Habib *et al.*, 2019; Pedro *et al.*, 2021). IPRs can foster investment in research, development, technology and innovation, which in turn might enhance production (Mercedes and Nuvolari, 2021; Yang *et al.*, 2020; Hamm *et al.*, 2020).

Excessive IPR can also be a barrier to the transfer of clean technologies in developing countries (Hilty *et al.*, 2020; Dai, 2020; Pearson, 2017). This is because developing countries are characterized by low capital levels, a lack of skilled workers and inadequate infrastructure *inter alia*. Weak IPR can also have adverse effects on innovation and consequently economic development. IPR can have negative effects on socioeconomic rights such as the rights to health, food, housing and education, especially in economically vulnerable countries (Lennhammer, 2020; Nomani *et al.*, 2020). For instance, if patent rights are issued for medical or agricultural inventions, it implies that inventions that could be used for helping vulnerable groups to be able to exercise their rights, are not readily accessible but are accessible to only those who can afford them. Consequently, approximately 75 percent of the world's population is health deficient and medicine starved due to patenting requirements of pharmaceutical industries (Nomani, 2020). Thus, for a country to benefit from the IPR protection system, the IPR system should match the phase of the economic and technological development of the country. This is critical, particularly for developing nations (Yan *et al.*, 2020; Amassoma *et al.*, 2020). Of importance is understanding the IPR system from a national, regional and global standpoint. This can start with the realization and manipulation of the fact that IPRs expire (Sharma and Kumar 2018). Most IPRs give the owner of the IP exclusive rights over a limited period after which other people are free to copy or use the IP free of charge. They can even make better proceeds or returns than those made by the inventor. This is because resultant products may have a lower price than that of the inventor since there can be lower development costs.

IPRs can result in new products of higher value, improving national economies. This is because new ideas and technologies are considered to be the primary source of economic

growth in the modern world (Sharma and Kumar, 2018). IPRs have had positive impacts on the foreign direct investments of countries such as China (Dai, 2020). Consequently, IPRs have attracted considerable attention from both policymakers and academics due to their macroeconomic effects. In the absence of protection, innovators can be discouraged from using their knowledge to benefit society. This is because they will have less or little to benefit. The absence of IPR protection can result in income losses to innovators. However, to obtain value from IPRs, there is also a need to consider factors such as licensing, market structure, consumers' preferences and competition from substitute products or services (Correa, 2020).

Of increasing importance are biotechnology-based IP and IPR. These cover plant, animal, food, pharmaceutical and fermentation biotechnology *inter alia*. However, Zimbabwe, though better than some Sub-Saharan countries in terms of biotechnology, is largely into traditional biotechnology (Sharma and Kumar, 2018; Correa, 2020). This trend is, however, changing with the increase in biotechnology students, graduates and research (Shoko *et al.*, 2018).

IP generation rates in biotechnology are compounded by the rapid increase in data generation and its availability via open-source platforms. This includes data from RNA and DNA sequencing, functional genomics experiments and macromolecular structure determination (Bamborschke *et al.*, 2021; Shoko *et al.*, 2018). This is driving research and product development through low-cost *in silico* studies. Some of the studies are conducted *de novo*. The ever-decreasing costs of genome sequencing, improvements in sequencing technology, assembly methods, and computational resources aid this rapid increase (Colleta *et al.*, 2021; Bamborschke *et al.*, 2021; Rossetto *et al.*, 2021). These data can be IP, while more IP can be developed from it when researchers collect, manage, and sift through it to derive new scientific insights.

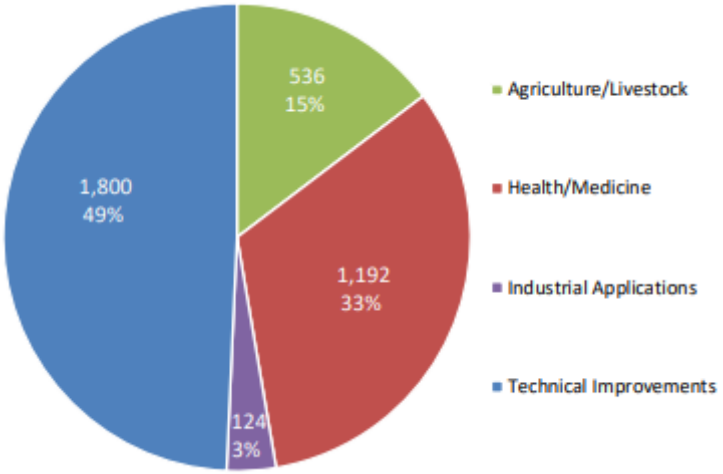
More IP and IPR can be generated from areas that Zimbabwe has recently prioritized such as medicinal cannabis (MC). Elsewhere, MC patents and plant breeders' rights (PBR) registrations have been filed on industrially applicable aspects. Some of the filed and granted patents are agricultural technologies targeted at improving the yield, efficiency and quality of cannabis. They cover original novel and applied MC research in areas including protection of the cannabis crop, harvesting and postharvesting of cannabis, new varieties and *ex*

planta and *in planta* cannabis gene expression. Other patent applications on MC target MC patient-oriented products and delivery systems for different diseases (Wyse and Luria, 2021). In Zimbabwe, PBRs are manifested in the PBR Act Cap 18: 16 of 1971. The Act is implemented by the Seed Services Institute. However, patents, copyrights and trademarks' applications are done through the Zimbabwe Intellectual Property Office (ZIPO) in Harare. The PBR Act has provisions for the acknowledgment of achievements of plant breeders of new varieties and protection of their exclusive rights based on uniform and well-defined principles. The plants eligible for protection are outlined in the PBR regulations of 1974. They include trees, agricultural crops, horticultural crops and ornamental crops. New legislation to cover other plants that may not be in these categories is needed. Typically, new varieties of annual crops are protected for 20 years, while perennial crops are protected for 25 years.

Zimbabwe and the sub-region are gifted with a large diversity of wild plants, cultivated crops and livestock species waiting to be improved (Magwede *et al.,* 2018; Cock *et al.,* 2018; Cock *et al.,* 2019, Nieman *et al.,* 2019). Several plant species have been explored for their medicinal potential, although with no subsequent channeling into industrial products. Plants such as *Cassia abbreviata*, *Dichrostchys cinerea* and *Bidens pilosa*, among others, have been used in folk medicine and have been proven to contain potent biotics that need biotechnological exploration and harness them into tablets or medicinal syrups (Shandukani *et al.,* 2018; Jobe *et al.,* 2018). Furthermore, several macrofungal species have been proven to have medicinal properties and patents to that effect have already been filed (Davis *et al.,* 2020). Macrofungi, both cultivated and uncultivated, have been used for ages in Chinese folk medicine (Zenebe and Krishna, 2020; Kotowski, 2019). Most of the same macrofungal species found to be medicinal also grow in Zimbabwe, making them amenable to development into value-added medicines. Conventional breeding coupled with genomic selection can be used to improve animal breeds in Zimbabwe. This includes goats, sheep, pigs, cattle rabbits and chickens, *inter alia*. Of increasing interest are wild animal species that have not been selectively bred. Stud breeding has to be taught and decentralized to small farmers in villages. The resulting breeds of choice can be maintained, used internally, or exported. New breeds can be registered with the Zimbabwe Herd Book or other registered breed societies. (Dube-Takaza *et al.,* 2021).

Additionally, genome editing tools such as clustered regularly interspaced short palindromic repeats (CRISPR), a 2020 Nobel Prize-winning technology, can be used to develop new IPs and consequently secure IPRs (Mudziwapasi *et al.*, 2018). CRISPR-based inventions have been made in a very short time in industrial biotechnology, therapeutics, foods, crop engineering and in developing tools for the manipulation of many living organisms (Jefferson, 2021).

CRISPR Patent Families by Category Earliest Priority Date December 31, 2018 (N = 3,652)

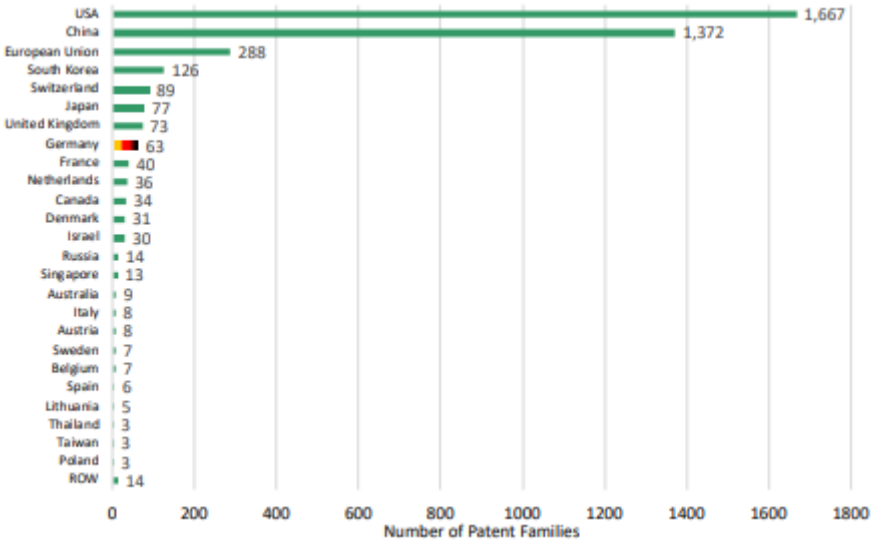


(Samantha and Cassidy, 2021)

Figure 1: Percent of CRISPR patent families by application category

These patents are mostly shared by very few groups and countries. Many African countries, including Zimbabwe, are not very active in the genome editing race (Ganguli, 2021; Jefferson, 2021). This is illustrated in figure 2.

Total CRISPR Patent Families by Country of Applicant Earliest Priority Date by December 31, 2018 (N = 4,026)



(Samantha and Cassidy, 2021)

Figure 2: Count of CRISPR patent families worldwide

Note: Patent families can have applicants in more than one country, and the family is counted once for each country represented, so some families will be double-counted. Attribution is not proportional. The European Union includes the United Kingdom.

Of increasing interest in Africa are plant varieties. Zimbabwe is well positioned to develop plant varieties using biotechnology tools such as molecular markers and genome editing. It possesses the relevant infrastructure and human resources. Below is a figure showing the increase in IPR related to plant varieties in developed countries and developing countries. Zimbabwe is among the developing countries.

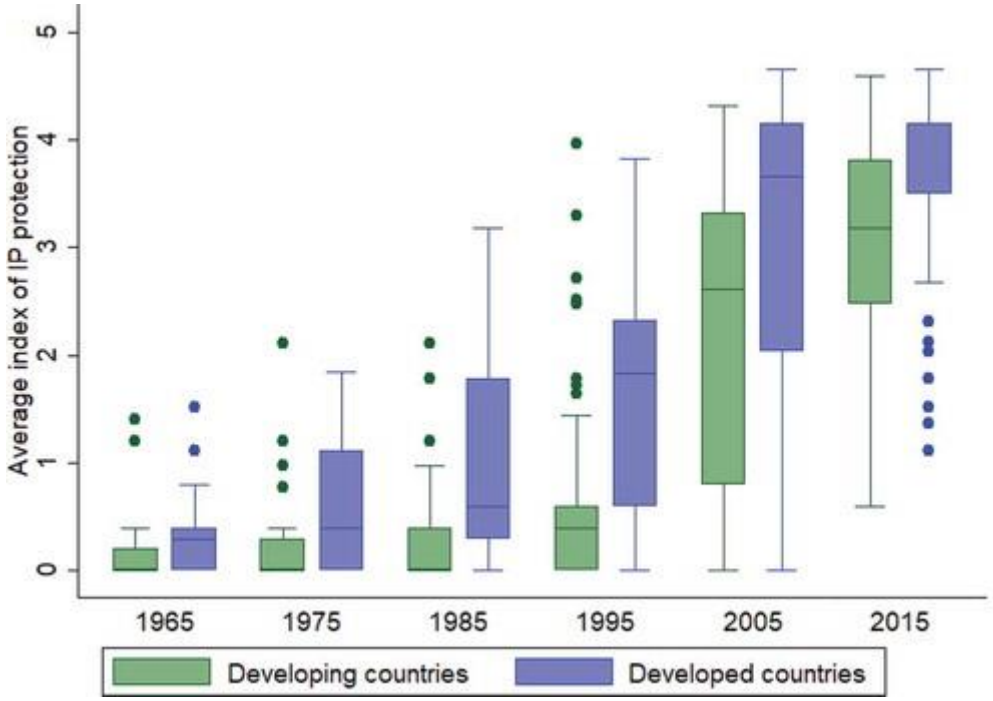


Figure 3: Evolution of IP protection for plant varieties for 41 developed countries (DCs) and 63 developing or least developed countries (LDCs) in selected years between 1965 and 2015.

Developing countries have been increasing their levels of IP protection since 1995. This could be due to the signing of the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Several countries implemented the demands of the TRIPS agreement swiftly well before the expiration of the transition periods granted to them. This is now possibly fostering the development of IP in countries. However, there were low levels of increases in developing countries' gross domestic product (GDP) per capita in response to high levels of IP protection.

In Zimbabwe, IP filings are lodged through the Deeds Companies and Intellectual Property Department. However, according to World Intellectual Property Organisation (WIPO) rankings, Zimbabwe's IP patent filings locally and regionally only added up to 18 for the period 2011 to 2020, which compares adversely with other countries (117 for Zambia for 2010 – 2019 period; 191 for Mozambique for period 2010 – 2019; 94 for Botswana and over 19000 for South Africa for period 2010 – 2019) (https://www.wipo.int/directory/en/). With this grim picture in locally conceived patents, Zimbabwe must exploit available expired patents to compensate for its poor showing in homegrown patents. Biotechnology innovations

can help change the status quo and contribute to economic development. This includes genetic engineering and non-genetic engineering-based innovations. It is, however, important to note that the WIPO list on Zimbabwe's patent filings is not exhaustive. There might be many other patents that are not captured on the list for various reasons.

Table 1: Zimbabwe's IP filing from 2010 to 2019

Year	Patent	Trademark (class count)	Industrial Design (design count)	GDP (Constant 2017 US$)
2010				28.86
2011				32.96
2012		450		38.45
2013		370		39.22
2014		322		40.15
2015	9	307		40.87
2016	9	244		41.18
2017				43.11
2018				45.19
2019				41.53

P Filings (Resident + Abroad, Including Regional) and Economy
(https://www.wipo.int/ipstats/en/statistics/country_profile/profile.jsp?code=ZW)

A resident filing refers to an application filed in the country by its resident, whereas a non-resident filing refers to the one filed by a foreign applicant. An abroad filing refers to an application filed by a country's resident at a foreign office. Most patent applications in Zimbabwe are from non-resident filings followed by abroad filings. Most of the patent grants are to abroad filings. Most utility model filings are from abroad filings. Most trademark filings are from non-resident filings followed by resident filings. Most utility model applications and grants are from abroad filings. Most of the applications are made via the Patent Cooperation Treaty (PCT) system followed by the Hague system and few to no applications are made via the Madrid system (www.wipo.int). Most applications are for trademarks. A strengthening of collaborations among resident, non-resident Zimbabweans

and Zimbabweans living abroad can bolster the number of IPR applications and grants. There is also a need to promote research that can potentially lead to IPR in Zimbabwe. This can be done by skewing the local requirements for funding by organizations such as the Research Council of Zimbabwe and universities *inter alia*. Increasing awareness of the IPR system and its benefits can also promote the generation of commercialisable IPs. Of increasing interest are biotechnology research and biotechnology-based innovations which have a high probability of obtaining IPR grants.

Studies by Munyawarara and Govender (2020) show that biotechnology is indeed a viable developmental tool, particularly for small and medium-scale enterprises of Zimbabwe. With the support and guidance of relevant departments of Zimbabwe's universities, the development of biotechnology innovations to also service and grow large-scale enterprises within the context of national and sub-regional industrial policies is a real possibility. This paper thus explores the status of biotechnology-based IPR in Zimbabwe and strategies that can be employed to increase biotechnology-based IP and IPR. Nevertheless, the acquisition of more up-to-date biotechnological equipment is essential to keep pace with developed world standards, which should provide part of the larger market for biotechnology products.

Laws governing biotechnology in Zimbabwe: Implications and opportunities

Pieces of legislation governing IP in Zimbabwe include,

- Armorial Bearings, Names, Uniforms and Badges (Amendment) Regulations, 2020 (No. 14).
- The Copyright and Neighbouring Rights Act Chapter 26:05 (2004)
- The Geographical Indications Act Chapter 26:06 (2001)
- Industrial Designs (Amendment) Regulations, 2020 (No. 15).
- The Integrated Circuits Layout-Designs Act, Chapter 26:07 (2004)
- The Patents Acts Chapter 26:03 as amended up to Act No. 14/2002
- The Trademarks Acts Chapter 26:04 (2001)

(Adapted from Shonge *et al.*, 2018)

NB. There is currently no Sui Generis system for utility models in Zimbabwe. Geographical Indication Regulations, 2016 were promulgated through Statutory Instrument 70/2016, gazetted on the 8th of July 2016 to operationalize the GI Act.

The policy document, Zimbabwe National Intellectual Property Policy and Implementation Strategy (ZNIPPIS) 2018-2022 aims to enhance socioeconomic and cultural development by in part utilizing its diverse IP assets. The government of Zimbabwe through the Ministry of Justice Legal and Parliamentary Affairs promotes interactions among innovators, researchers and industry as a way to promote innovation. It seeks to proactively prevent leakages of patentable research results and protect and promote the commercialization of traditional knowledge. Of particular interest is the pharmaceutical industry (Shonge, 2018).

The 1980 Lagos plan supports the creation of regional institutions to support industrialization, including universities (Bawa and Ateku, 2020). In 2013, the Southern African Development Community (SADC) Council of Ministers approved the SADC Industrial Development Policy Framework in 2015 the SADC Industrialisation Strategy and Roadmap 2015-2063 and in 2017 an Action Plan for the SADC Industrialisation Strategy and Roadmap Potential for benefit and industrialization from expired IPR for Zimbabwe (https://www.wipo.int/directory/en/).

Most developing countries, including Zimbabwe, have progressive industrial development policies (Campi *et al.*, 2019). The Zimbabwe Industrial Development Policy (ZINDIP: 2019 – 2023) includes specific sections, 3.2, 3.5, 3.6 and 5.4, which emphasize innovation and value addition for agro-based products and indigenous herbs using IP. The policy further mentions biotechnology as an intended focal area to drive industrial development. This policy dovetails with the SADC Industrial Development Policy, approved in 2013, which promotes innovation for industrial development (SADC 2013 - 2018).

Zimbabwe joined the Food and Agriculture Organisation (FAO) on 7 November 1981. It has been a member of the World Trade Organisation (WTO) since 5 March 1995. Zimbabwe adhered to the International Plant Protection Convention (IPPC) on 30 November 2012 without any declarations or reservations. Zimbabwe is also a member of the Office International des Epizooties (IOE)/World Animal Health Organization. Zimbabwe has a national biotechnology policy that was developed in 2005 under the United Nations Environment Programme (UNEP)/Global Environment Facility (GEF) Global Project for the Development of National Biosafety Frameworks. This policy helps regulate the development

and use of biotechnology and its products. Through these policies, Zimbabwe recognizes that biotechnology can play a critical role in:

- National food security.
- Sustainable exploitation of the country's biological resources.
- Climate change alleviation.
- Improvement of health delivery.
- Provision of renewable bioenergy, food and beverage industries.
- Biodiversity conservation.

The national biotechnology policy provides for harnessing biotechnology to provide for:

- Agricultural development.
- Improvement of human health.
- Promotion of industrial development.
- Provision of affordable green energy.
- Sustainable management of the environment.

In 2005, the Government of Zimbabwe also agreed through the National Policy on Biotechnology to allocate 0.5% of its GDP towards the development of biotechnology, biotechnology research, its application and regulation. Consequently, the National Biotechnology Authority Act [Cap. 14:31] of 2006 which established that the National Biotechnology Authority (NBA) was passed to reinforce the policy framework. The effect of the NBA Act of 2006 was also to replace the Research Amendment Act of 1998 and to repeal the Research (Biosafety) Regulations of 2000. Consequently, NBA replaced the Biosafety Board. The National Biotechnology Act [Cap. 14:31] of 2006 governs:-

- All activities aimed at research into and the development, importation, exportation and use of biotechnological processes;
- The import, export, contained use, release, or placing on the market of any product of biotechnology that is likely to harm human health, the environment, the economy, national security, or social norms and values;
- Any activity involving biological and molecular engineering technologies such as metabolic engineering, proteomics, metabolomics, nanotechnology, genetic

modifications, cloning, DNA-chip technology, bioinformatics and other technologies as may be declared by the authority to constitute potentially harmful research or undertakings;

- All measures aimed at minimizing the impact of biotechnological processes on national security, human health, animals, plants and the environment;
  (https://nba.ac.zw/policies.php)

However, deliberate release or commercialization of products of genetic engineering (GE) is currently not allowed in Zimbabwe. Research up to field trials is allowed. This means that researchers can develop products of GE test them and apply for IPR even outside the country. These applications can be made via the African Regional Intellectual Property Office (ARIPO) or the PCT system. This IP, although it cannot be used in Zimbabwe, can be sold to other countries, allowing commercialization of GE products. Additionally, collaborations with biotech companies in those countries or the establishment of completely new companies in those countries can be pursued to realize economic and social value from the IP. Patent Scope gives Zimbabweans access to thousands of patents that they can use as prior art (https://patentscope.wipo.int/search/en/search.jsf). Scientists from Zimbabwe can work in International Centre for Genetic Engineering and Biotechnology (ICGEB) facilities dotted around the world since Zimbabwe is a member of ICGEB. Here, they may generate IP and subsequently apply for IPR without much prejudice.

Domestic laws and institutions regulating the crop seed industry

The crop industry in Zimbabwe is regulated by the Seed Act of 16 August 1971, Statutory Instrument (SI) 661/1971 on seed regulations, Plants Pests and Diseases Act of 1 January 1959 and SI 48/1980 on Plants Pest and Diseases regulations.

The crop seed industry is supervised by the Plant Protection Institute established under the Plant Pests and Diseases Act. This Act is implemented by the Lands, Agriculture, Fisheries, Water and Rural Resettlement. This is done through the Department of Research and Specialist Services under the Seed Services Institute established under the Seed Act, the Chemistry and Soil Institute and the Plant Quarantine Services established under the Plants Pests and Diseases Act. These institutes regulate the importation of harmful species, seed export and seed import. Importation of GM seed varieties is generally not allowed in

Zimbabwe. As a member of the WTO, a signatory to the Agreement on Sanitary and Phytosanitary Measures and having ratified the IPPC, Zimbabwe follows the international phytosanitary standards that were codified in the Plants Pest and Diseases Act. Under these regulations, it can be difficult to import GM seeds save for research, as provided for under the Biotechnology Act.

Expired patents

There are a multitude of biotechnology patents that have expired in the long, medium and short term. Many of these patents have yielded results to patent holders and industry in their respective countries of inception and registration. Scientists in developing countries can benefit from expired patents as a means to develop their local industry. The operationalization of expired patents cannot be divorced from both national and regional industrialization for effective tapping of these patents. We bear in mind, however, that actioning of IPRs is difficult to boost the industrial development of developing countries largely due to underdeveloped technology and ineffective industrial policies (Campi *et al.,* 2019). Expired patents mean the original patentee no longer holds the right to raise patent infringement claims as found with Monsanto's Roundup Ready patent which expired in 2015 (Jefferson *et al.,* 2015), while first-generation biotech medicines are now off-patent (Lokko *et al.,* 2017). A particularly attractive opportunity is the development of biosimilars through taping from expired patents. In view of industrial development to address UN SDG No 9 (to promote inclusive and sustainable industrialization and foster innovation), however, developing countries face limited skilled intellectuals together with limited technology to implement such patents (Lokko *et al.,* 2017). It is with these limitations that scientists must strive to contribute to industrial development for developing nations using the wide-open opportunity in expired patents.

Bioethics concerns with IPR

Bioethics is the study of moral issues emerging from advances in biology and medical policy and practice (Prestre, 2017; Bhatia, 2018; Lorenzo, 2018). Modern biotechnology industries play a prominent role in this fourth industrial revolution. These industries usually use biological resources as basic raw materials and they cover inventions related to genetic resources, such as gene sequencing and microorganisms (Prestre, 2017; Bhatia, 2018; Capps *et al.,* 2018).

Science should be done fairly, objectively, without aspiring for personal benefit and self-promotion, honestly in conclusions, just to associates, persistently in accuracy, never to modify or invent data and not to catch hold someone else's IP (Kuersten, 2018; Hilgartner, 2018; Capps *et al.*, 2018). In early history, patent policy did not protect living things but this policy is changing along with the massive development of modern biotechnology (Kuersten, 2018; Hilgartner, 2018 Kumar *et al.*, 2019).

Can IPR be expanded to include biological resources?

Patenting biological substances is regarded as a mistake, both morally and economically, for any system of IP and should be reanalyzed at all levels, particularly as it affects developing nations (Bandyopadhyay, 2018**;** Barizah, 2019; Barizah, 2020). The expansion of the IPR, particularly to include biological resources, including life forms, might facilitate the biopiracy of developing countries' resources and such a condition can potentially affect the availability of public goods on the basis that those important resources can be privatized under a global IPR framework by biotechnology industrialized countries (Muzaka, 2018; Smith, 2019; Asid, 2019). Patent granting related to genetic resources also leads to the principles of protectability, patentability, predictability and certainty of the modern patent system being in question. Martin Khor also argues that the large-scale patent granting for genes and other biological materials leads to an even greater concentration of control over the world's food crop by a few corporations and that these patents pose a threat to global food security, including farmers' livelihoods. Those supporting patenting of life forms argue that considerable ingenuity is involved in locating, isolating and describing molecular biological matter, which was until then unknown to the world, and these forms have industrial utility (Prestre, 2017; Bhatia, 2018; Lorenzo, 2018). The extension of patentable subject matter to include biological resources based inventions is regarded as unfair, while international patent policy does not provide a measure to balance the interest of both biotechnologically rich developed nations and biodiversity-rich developing nations (Kuersten, 2018; Hilgartner, 2018; Capps *et al.*, 2018).

Can isolation or purification of genetic resources be considered an inventive step?

There is great concern relating to the global regime of IPR protection related to biological resources, which potentially facilitates the misappropriation of biological resources from developing countries (Kumar *et al.*, 2019; Barizah, 2019; Barizah, 2020). In biological

inventions, the question is whether isolated or purified genetic resources can be considered an inventive step or non-obvious to a person skilled in the art (Muzaka, 2018; Smith, 2019; Asid, 2019). The first approach strongly argues that there is no inventive step in the isolation of genetic materials, while the second approach argues that an inventive step is required to isolate genetic materials. For example, Myriad Genetics and its partners' patents on the BRCA1 and 2 breast cancer genes were revoked or altered mainly due to the lack of an inventive step after court challenges. It is important to note that the standard of the non-obviousness test in the US is very low compared to that in Europe. This affects the possibility of a patent being granted (Bandyopadhyay, 2018**;** Barizah, 2019; Barizah, 2020**).**

Isolating a genetic sequence may be regarded as non-obvious even when the prior art discloses the structure of the protein of the claimed gene and the general methods used for such isolation (Shadlen and Sampat, 2018; Franjić, 2018; Wyse and Luria, 2020). Meanwhile, Australia takes the view that to meet the inventive step assessment, biological materials-related inventions must involve "the technical intervention of a technologist applying their inventive ingenuity to produce something distinguishable from natural source material". This means that each jurisdiction applies different standards to test the inventive step but based on the above approaches, it is difficult for genetic resources-based inventions to fulfill the criteria of inventiveness (Bandyopadhyay, 2018**;** Barizah, 2019; Barizah, 2020**).** These are the reasons why such patents are regarded as having the potential to facilitate misappropriation of biological resources of developing countries, without disclosure requirements, and fair and equitable benefit sharing given to the country of origin and the community that has conserved such resources from generation to generation (Bhatia, 2018; Muzaka, 2018; Akram *et al.*, 2019).

Are the developing countries inherently disadvantaged?

Most innovations originate in developed countries. IPRs tend to confer privileges to producers rather than consumers. This ultimately gives developed countries an advantage. First, strong patents may lead to strong monopolies, which, in turn, may encourage high prices and consequent unaffordability of patented materials such as drugs by the poor (Muzaka, 2018; Smith, 2019; Asid, 2019**)**. Second, by preventing local manufacture or parallel importation of cheaper generic products such as drugs, governments are incapacitated from arranging alternate affordable supplies (Muzaka, 2018; Asid, 2019; Blouin-Genest and

Erb, 2019). These negative impacts are widely recognized for their serious implications to the public health and development needs of many poor developing countries. How much such a strong patent regime would be helpful to developing countries in gaining access to products such as existing drugs and for developing new drugs for better healthcare, is disputable (Bandyopadhyay, 2018**;** Barizah, 2019; Barizah, 2020**).** There is a large body of evidence from developed countries that prices of patented drugs are quite high and that prices fall steeply as soon as the patent is expired and generic producers enter the market. Even without patents, it is difficult for many poor people to access the necessary drugs (Shadlen and Sampat, 2018; Franjić, 2018; Wyse and Luria, 2020). There is thus a need to ensure drug affordability and availability to preserve life.

Broadened patents on process and product

Other ethical issues arise from the broadened patents on process and product, evergreening patents under the legal subtleties of patent rules, and large-scale patenting of DNA sequences and gene-based diagnostic technologies (Bhatia, 2018; Muzaka, 2018; Shadlen and Sampat, 2018.). Liberal patents on products and processes with broadly claimed subject matter virtually exclude a broad area for further innovation and facilitate augmenting the monopoly of the patent holder on the area. Patents held by the US company Myriad Genetics on the BRCA1 gene, which is linked to susceptibility to breast cancer, virtually stop others from developing alternative diagnostic tests (Bandyopadhyay, 2018**;** Barizah, 2019; Barizah, 2020**).**

On which grounds is compulsory licensing granted?

The other ethical issue is the legal hurdles being erected before developing countries on their rights to determine the grounds on which compulsory licensing is granted and the right to determine what constitutes a national emergency or other circumstances of extreme urgency (Graeff *et al.*, 2018; Lorenzo, 2018; Wahid, 2019). These hurdles are covered under the Doha Declaration. These are important exceptions that seek to make necessary drugs affordable during times of epidemics, mass suffering and death (Chapman, 2018; Boggio and Calvin, 2018). Compulsory licensing benefits developed and developing countries. It can help scale up production and improve the availability of drugs (Perehudoff *et al.*, 2021). The formation of public-private partnerships and joint collaboration with governments in times of

emergency can help reduce the impact of losses incurred by Big Pharma during the research and development of medicines such as those for COVID-19 (Elekwa, 2021).

Drug development and clinical evaluations

The ethical issues associated with drug development and clinical evaluations involve the use of poor people in developing countries without proper informed or genuine consent (Shadlen and Sampat, 2018; Franjić, 2018; Wyse and Luria, 2020). Several unethical instances have come to light where drug evaluators have contracted poor subjects from developing countries for clinical evaluations for which subjects' informed consent is not available in developed countries, or the clinical trial on the specific test molecule is not permissible under bioethics guidelines of these countries (Graeff *et al.*, 2018; Lorenzo, 2018; Wahid, 2019). A more recent clinical evaluation, which stirred up the concern of medical professionals and bioethical bodies, pertains to the evaluation of zidovudine, an anti-HIV drug for pregnant mothers, conducted by US researchers on African pregnant mothers (Lorenzo, 2018; Wahid, 2019; Blouin-Genest and Erb, 2019).

Patenting whole biotechnologically bred organisms

The most unethical aspect of patenting whole biotechnologically bred organisms instead of changes made in one or a few genes is that many thousands of unmodified native genes present in the genome of the patented organism are excluded from the reach of other researchers, although the patent holder has no innovation claim on these genes (Graeff *et al.*, 2018; Lorenzo, 2018, Wahid, 2019). Even in recombinant DNA technology, the genes involved are not invented but recombined in a manner that does not happen in nature, therefore, ethical practices in science demand that genetic resources used in agriculture be excluded from the IPR regime (Chapman, 2018; Boggio and Calvin, 2018). Treating genes as patentable inventions is more a reflection of ignorance than of insight. It represents greed for the appropriation of a public entity thus the multiple patenting in agricultural biotechnology is already causing problems for research advancement, which may be well illustrated with 'golden rice' (Carson and Cade, 2019; Contreras, 2018; Sary, 2020).

Inconsistencies with the Convention on Biological Diversity (CBD)

Another ethical dimension introduced by the IP protection on living entities mandated by TRIPS is its inconsistency with the CBD and the recognition of the right of local

communities to biological resources (BRs) and associated traditional knowledge (TK) (Brahmi, and Tyagi, 2019; Muzaka and Serrano, 2019; Hahn, 2020). This inconsistency promotes the piracy of BRs and TK from many developing countries (Carson and Cade, 2019; Contreras, 2018; Sary, 2020). TRIPS is unifocal in ensuring the IPR on 'innovations' based on BRs or associated TK, with an apparent assumption that the related prior art, as material or knowledge, is freely accessible with no legal encumbrances. Such an assumption ignores the legally binding major provisions of CBD on national sovereignty over BRs and TK *inter alia*. It also ignores the responsibility of the state on the facilitated access to them with prior informed consent and the requirements of parties accessing them and establishing IPR on them (Muzaka and Serrano, 2019; Hahn, 2020; Cockbain and Sterck, 2020). However, the Swakopmund Protocol on Traditional Knowledge and Expressions of Folklore is set to try and address the above concerns. A few countries are now party to the protocol. These include Zimbabwe, Zambia, Rwanda, Botswana, Namibia, Malawi, Liberia and the Gambia.

IP protection of plant varieties

Another important ethical issue arises from the often-made claim that IP protection of plant varieties stimulates higher private investment in crop improvement research, which benefits all farmers, including the poor in developing countries **(**Gebrehiwot, 2018; Dutfield, 2018; Muzaka and Ramon, 2020**)**. The benefits possible are on two counts. First, due to the availability of better varieties and consequent economic gains accessible to farmers through their cultivation, the benefit share is eligible to concerned communities with the commercialization of products or processes developed from the BRs and TK conserved by them (Carson and Cade, 2019; Contreras, 2018; Sary, 2020). However, many concerns arise concerning the use and pricing of the new varieties.

IPR Regimes and Protection of TK

There are concerns about defining what is to be protected, who the 'beneficiaries' should be and which forms of TK should be included for protection under the law **(**Priya and Kurian, 2018; Tsioumani, 2018; WIPO, 2018). In the case of TK, only that which is held secret by healers/communities or that which is in texts or the public domain as common knowledge should be protected (Carson and Cade, 2019; Contreras, 2018; Sary, 2020). Northern countries are attempting to use as restrictive a definition as possible for what TK is to be

protected with 'like-minded countries', arguing for the most inclusive definition for protection of all three tiers of TK **(**Priya and Kurian, 2018, Tsioumani, 2018; WIPO, 2018). Once outside protection, commonly used TK may, with minor 'innovations', become patentable and monopolized, given the extent of erroneous patents and international contestations to the existing protections under national laws. However, in Zimbabwe, there have been very low to no contestations. The scope of protection to be offered would be based on a tiered approach, depending on the form of TK but given the diversity of healers and forms of TK, defining each tier of TK and its holders will pose a challenge **(**Gebrehiwot, 2018; Dutfield, 2018; Muzaka and Ramon, 2020**)**. Beyond indigenous and local communities, the question remains whether nations and national authorities should be mandated as custodians of TK and even if nations are recognized, should they have a fiduciary role or should communities retain decision-making rights (Munshi and Sharma, 2018; Carson and Cade, 2019; Contreras, 2018). Organizing communities into groups for purposes of benefit sharing and easy allocation of IPRs based on TK should be managed well to avoid negative events.

Strategies for promoting IP generation

There is a need to create more awareness of IP, IPR and international trade among citizens. This can help the country benefit from initiatives such as the African Continental Free Trade Area (AfCFTA). This is a free trade area for 54 of the 55 African Union member countries. It was founded in 2018 and trade commenced on 1 January 2021. The commercialization of IP can also be pursued under the African Union's Agenda 2063. This agenda prioritizes science and innovation-driven manufacturing, industrialization, value addition, economic diversification and sustainable use of biodiversity. The AU Science, Technology and Innovation Strategy for Africa 2024 (STISA-2024) also prioritizes science, technology and innovation for the socioeconomic development and growth of Africa. The Continental Strategy for Geographic Indicators (GI) in Africa (2018 - 2023) seeks to enhance GI stakeholders' networking at a national level, preservation and promotion of traditional products on local markets and positioning them on international markets. The African model law for the protection of the rights of local communities, farmers and breeders, and for the regulation of access to biological resources can be harnessed by communities to derive benefits from the IPR system. There is thus a need to create platforms to link innovators in Zimbabwe with other innovators on the continent to promote IP generation and inter and intra

country trade and industrialization. This will help derive value from the provisions of AfCFTA, AU's Agenda 2063 and STISA.

Early training of children in computer programming to enhance their bioinformatics and proteomics skills should be promoted. Lessons can be taken from America's 4-H program. This program is based on the belief that the best way for children to learn is by doing. Under the program, children complete hands-on projects in areas such as science, health and agriculture *inter alia*. The children receive guidance from adult mentors while being encouraged to take on proactive leadership roles. Public universities, volunteers and professionals can help mentor children (www.4-h.org). The advantage is that most bioinformatics and proteomics software are available for free. However, data costs for some of the internet operations are still high. Initiatives such as Edu-zone, which provides free internet access to universities can be expanded to cover this initiative. Additional lessons can be learnt from Shoko et al. (2018). More educational programs in biomedical engineering are consequently needed. These will produce engineers that can collaborate with biotechnologists in developing and maintaining machinery to support biotechnology-based initiatives. Of importance in engineering programs should also be microfluidics which has utility in biotechnology equipment.

The IPR system should be translated to all locally recognized languages, simplified and explained using all forms of media available to the state. IPR should be taught early in life through initiatives such as cartoons, movies, dramas and songs. This will make it easy for communities to understand the system and easily benefit from it. More tertiary programs should have components of IPR since there is low awareness of them in the country.

The establishment and funding of more innovation hubs in the country can also help increase IP and IPR generation. The government of Zimbabwe is already driving this initiative in line with its Vision 2030 and the National Development Strategy 1. However, these must also be decentralized and allow the participation of citizens outside tertiary institutions. Additionally, business incubation programs should be put in place. These will help ensure that new businesses have a low failure rate and can comply with the country's laws *inter alia*. The business should be linked to markets and be supported by government policies to promote the uptake of their products and hence their success.

Seed capital should also be available to new businesses from innovation hubs. Many funding initiatives can be pursued. These include the provision of prize money in competitions, grants, loans and equity-based financing (Baker *et al.*, 2017). Similar initiatives such as the Impact HUB, Green Enterprize and Youth Konnect *inter alia* are there in the country. They are commonly conducted in collaboration with the Ministry of Youth, Arts, Sports and Recreation. Zimbabwean youth are also participating in programs such as the Mandela Washington Fellowship which has a Business and Entrepreneurship track where they network with other youth in business from across the continent and USA. These programs are being funded by organizations such as the International Labor Organization (ILO), United Nations Development Programme (UNDP), the US Department of State and banks *inter alia*.

In conclusion, bioethical considerations for the safe regulation and fair use of biotechnology products for the welfare of humankind and nature are of paramount importance. Zimbabwe can extract much socioeconomic value from it. Many strategies for increasing the generation and commercialization of IPs and IPRs should be pursued for the nation to benefit from the IPR system.

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