المعهد القومى للملكية الفكرية
The National Institute of Intellectual Property
Helwan University, Egypt

المجلة العلمية للملكية الفكرية وإدارة الابتكار

دورية نصف سنوية محكمة يصدرها

المعهد القومي للملكية الفكرية

جامعة حلوان

العدد الخامس
ديسمبر ٢٠٢٢

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الهدف من المجلة:

تهدف المجلة العلمية للملكية الفكرية وإدارة الابتكار إلى نشر البحوث والدراسات النظرية والتطبيقية فى مجال الملكية الفكرية بشقيها الصناعي والأدبي والفني وعلاقتها بإدارة الابتكار والتنمية المستدامة من كافة النواحي القانونية والاقتصادية والادارية والعلمية والأدبية والفنية.

ضوابط عامة:

- تعبر كافة الدراسات والبحوث والمقالات عن رأى مؤلفيها ويأتي ترتيبها بالمجلة وفقا لإعتبارات فنية لا علاقة لها بالقيمة العلمية لأى منها.
- تنشر المقالات غير المحكمة (أوراق العمل) فى زاوية خاصة في المجلة.
- تنشر المجلة مراجعات وعروض الكتب الجديدة والدوريات.
- تنشر المجلة التقارير والبحوث والدراسات الملقاه في مؤتمرات ومنتديات علمية والنشاطات الأكاديمية في مجال تخصصها دونما تحكيم في أعداد خاصة من المجلة.
- يمكن الاقتباس من بعض مواد المجلة بشرط الاشارة إلى المصدر.
- تنشر المجلة الأوراق البحثية للطلاب المسجلين لدرجتى الماجستير والدكتوراه.
- تصدر المجلة محكمة ودورية نصف سنوية.

ألية النشر فى المجلة:

- تقبل المجلة كافة البحوث والدراسات التطبيقية والأكاديمية في مجال حقوق الملكية الفكرية بكافة جوانبها القانونية والتقنية والاقتصادية والادارية والاجتماعية والثقافية والفنية.
- تقبل البحوث باللغات (العربية والانجليزية والفرنسية).
- تنشر المجلة ملخصات الرسائل العلمية الجديدة، وتعامل معاملة أوراق العمل.
- يجب أن يلتزم الباحث بعدم إرسال بحثه إلى جهة أخرى حتى يأتيه رد المجلة.
- يجب أن يلتزم الباحث بإتباع الأسس العلمية السليمة في بحثه.
- يجب أن يرسل الباحث بحثه إلى المجلة من ثلاثة نسخ مطبوعة، وملخص باللغة العربية أو الانجليزية أو الفرنسية، فى حدود ٨ ـ ١٢ سطر، ويجب أن تكون الرسوم البيانية والإيضاحية مطبوعة وواضحة، بالإضافة إلى نسخة إلكترونية Soft Copy، ونوع الخط Romanes Times New ١٤ للعربى، و١٢ للا نجليزي على B5 (ورق نصف ثمانيات) على البريد الالكتروني: ymgad@niip.edi.eg
- ترسل البحوث إلى محكمين متخصصين وتحكم بسرية تامة.
- في حالة قبول البحث للنشر، يلتزم الباحث بتعديله ليتناسب مع مقترحات المحكمين، وأسلوب النشر بالمجلة.

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Protection of Intellectual Property Rights in the Plant and Pharmaceutical Biotechnological Fields: Comparative Study

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Protection of Intellectual Property Rights in the Plant and Pharmaceutical Biotechnological Fields: Comparative Study

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Abstract:

There is a lack in developing countries regarding protection of IPR related to plant and pharmaceutical biotechnology compared to developed countries. This study will introduce some successful examples of protection of IPR related to plant and pharmaceutical biotechnology in some developing and developed countries to be guided by them in our country. Objective of the study: 1- Identification of biotechnology, types of biotechnology, impact of biotechnology in economy of nations. 2- Studying different legal means of protection of IPR in plant and pharmaceutical biotechnological fields. 3- Comparative analysis of legal protection of IPR in plant and pharmaceutical biotechnological fields in both developed and developing countries. 4-Measuring the awareness regarding the legal protection of IPR in plant and pharmaceutical biotechnological fields in both developed and developing countries. 5-plant and pharmaceutical biotechnological innovation during crises (e.g., COVID-19) and its impact on fighting diseases and establishing Small and Medium Enterprises and governmental rules in this regard. 6- Crimes of IPR in both developing and developed countries. This study is based on a hypothesis that: there is a difference between developed and developing countries (including Egypt) regarding the protection of IPR in plant and pharmaceutical biotechnological fields and studying this difference will lead us to improve the situation in our country. Comparative Studies of different legal means of IPR protection in plant and pharmaceutical biotechnological fields in both developing and developed countries will be done. (Developing countries: Egypt, Nigeria, India and others

– Developed countries: USA, Australia, France and European Countries).

Key words: Protection of IPR – Innovations- Developing and Developed Countries – Plant and Pharmaceutical Biotechnology.

Introduction:

Intellectual Property Right (IPR) as defined by the FAO (2001) is intangible right which grants an exclusive right to impede others to freely exploit an invention or creation. These rights exist in various forms like patents; trademarks, industrial designs or copyrights. Each form has different implications and grants different rights. Patents for instance confer exclusive rights to their holders by granting a legal monopoly on a novel and useful invention. Patent is a government issued grant which confers on the inventor the right to exclude others from making, selling, using or offering for sale, or selling the invention for a period of 20 years, measured from the filing date of the patent application (Nwogu, 2014).

Biotechnology is the use of biological processes, organisms, or systems to manufacture products intended to improve the quality of human life. The earliest biotechnologists were farmers who developed improved species of plants and animals by cross pollenization or cross breeding. In recent years, biotechnology has expanded in its scope, and applicability. Biotechnology is the use of living organisms to make products or run processes, now biotechnology is best known for its huge role in the field of medicine, and is also used in other areas such as food and fuel. BREAKING DOWN 'Biotechnology' Biotechnology involves understanding how living organisms function at the molecular level, so it combines a number of disciplines including biology, pharmacy, physics, chemistry, mathematics, science and technology (Alam, 2022).

Biotechnology is a motor of technological advancement in both the developed and developing countries though at different levels in scope and content. One of the three new technologies that impact on our lives on virtually a daily basis in the international arena, biotechnology (and the life sciences) influence developments and issues in interactions between Europe and the USA, and between the developed and developing worlds (DaSilva *et al*., 2002).

The impact on developing countries of strengthening the IPRs as a result of the Uruguay Round TRIPS Agreement on genetic

resources is a sensitive issue at the centre of a polarized debate. Loss of biodiversity is the major global threat to the planet other threats being climate change and agrochemical pollution. Fears have been expressed that genetic resources originating in developing countries will be used for the development of new agricultural biotechnology based techniques and products by the industrialized countries, and to which biotechniques and bioproducts access would subsequently be restricted by IPRs. Also, it is argued that strengthened intellectual property rights would increase the flow of technologies and products from developed to developing countries, and would provide new incentives for local research and innovation. The consequences of strengthened IPRs for the crop biosecurity regime are likely to be uneven and differing among countries which have varying levels of development in plant biotechnology and capacities to stimulate innovation in agriculture. Impacts are also likely to vary from one crop to another, between commercial and food crops and amongst different groups of farmers. The genomics revolution, however, has provided an additional impetus to the debate about IPRs for crop safety and biosecurity. Most of the more advanced countries are expanding both their own technology base by developing and importing new biotechnologies. Some countries in Asia, Africa and Latin America are attempting to develop biotechnologies specifically directed to solving their agricultural problems through publicly funded national agricultural biotechnology research systems. Most developing countries, however, have not yet reached this stage in the development of agricultural biotechnology due to many tangible and intangible reasons in their research and development systems and their under-developed market infrastructure (Malik, K. and Yusuf, Z. 2005).

If developing countries are to benefit from the use of modern biotechnology in agriculture and want to increase the status of crop biosecurity then the key constraints such as bioterrorism and biopiracy, etc., within the research, technology development and delivery system need to be clearly identified with the introduction of appropriate policy measures (Ban, 2000).

The objectives of the study:

1- Identification of biotechnology, types of biotechnology, impact of biotechnology in economy of nations.

2- Studying different legal means of protection of IPR in plant and pharmaceutical biotechnological fields.

3- Comparative analysis of legal protection of IPR in plant and pharmaceutical biotechnological fields in both developed and developing countries.
4-Measuring awareness regarding the legal protection of IPR in plant and pharmaceutical biotechnological fields in both developed and developing countries.
5- plant and pharmaceutical Biotechnological innovation during crises (e.g., COVID-19) and its impact on fighting diseases and establishing Small and Medium Enterprises and governmental rules in this regard.

Spatial limits:

Developing countries: Egypt, Nigeria, India and others – Developed countries: USA, Australia, France, European Countries.

1-Protection of Intellectual Property Rights in the Biotechnological Fields: Developing Countries:

The majority of the population in developing nations depends on agriculture. Agricultural biotechnology involves genetic modification and promises a number of important benefits, such as improving agricultural yields by increasing the resistance of crops to pests and facilitating them to flourish in harsh natural environments, improving the productivity of crops, and reducing pesticide use. Also, concerns have been raised about the potential negative impacts of genetic modification. To promote research and development in agricultural biotechnology, intellectual property rights (IPRs) are one of the primary tools. Based on the fact that high investment is required to develop new genetically modified (GM) technologies and products, stronger intellectual property protection is necessary to stimulate research and to allow recovery of investment. As international rules increasingly raise the level of intellectual property protection, there is rising concern about the potential negative impacts on the dissemination of knowledge and important products, further Research and Development, food security, and the conservation of biodiversity among other fundamental areas of public policy (Prasad, R. *et al.,* 2012).

1.1. Egypt:

a- **Egyptian Patent Legal System (Sakr, M, 2019) :**

Starting with Law No. 132/1949, there have been several amendments in the course of developing Egypt's patent legal system • Now Law No. 82/2002 • Focused on amending and unifying the previously separate laws for patents, trademarks, designs and copyrights in line with TRIPS, which Egypt joined in 1995. Since

issuing Egypt IPR law (82) in 2002, sincere efforts have been done to improve the legal framework for IPR protection and enforcement, with the aim to attract more investment • Establishment of the Economic Court in 2008 has significantly affected the development in the area of IPR • After 2011 Revolution, and as a result of political instability, the governmental focus on IPR file has been significantly reduced • In 2014, Egypt started to regain its stability back and the government took decisive actions to boost technology transfer and commercialization and targeting knowledge based economy

• Issuing of Egypt law for STI incentives (law no.23) in 2018 can be considered as one of the main decisive actions towards creating enabling environment for innovation, better utilization of IPR and technology transfer EGPO was established in 1951, became an affiliated organization under the ASRT since 1971 • Deals mainly with patents and utility models • EGPO is active in Egypt's joining of various international agreements, for example: o Paris convention in 1951 o PCT in 2003 o WIPO in 1975 • In 2013, EGPO was the first office in the Arab region to be appointed as an ISA and IPEA.

IP Development Strategy - Egypt Vision 2030

A. Objectives: 1- Nurturing enabling environment for the localization of technology and production of knowledge. 2- Develop and promote an integrated national innovation system. 3- Connect knowledge and the innovation outputs with country priorities.

B. Expected Benefits in Economic Growth: 1- Increasing competitiveness 2- Providing new job opportunities. 3- Improve Egypt's position on the global market 4- Increase exports.

b-Egypt Needs a Biosafety Framework for Agricultural Biotechnology (Wally, A., 2018):

Despite Egypt's landmass of nearly 1 million square kilometers, only five percent of the area supports habitation while overlapping with cultivated areas. Less than four percent of the land area is arable. Water availability for human consumption and agricultural production is a major concern. Scientific and technological advances in agricultural production and biotechnology offer the possibility of economic development and crop improvement. Although Egypt lacks legislation regulating biotechnology, the government permits biotech imports so long as country-of-origin also consumes these products. FAS Cairo (Post) projects that Egypt will import 9 million metric tons (MMT) of corn

and 3.5 MMT of soybeans in calendar year (CY) 2018 to meet the feed demand of its growing poultry and aquaculture sectors (see, GAIN-EGYPT No. EG18020 – Grain and Feed Update 2018).

Egypt does not require labeling of biotech products. It sources corn and soybeans derived through GE, but prohibits planting of such crops. Egypt in 2008 was the first Arab country to commercialize a biotechnology corn crop (incorporating *Bacillus thuringiensis* (Bt) spores, providing the crop with an insect resistance trait). In March 2012, the Minister of Agriculture however suspended the planting of MON 810 due to an anti-genetically engineered (GE) products media campaign. Ministerial Decree 378/2012 suspends the registration, cultivation, and commercialization of all genetically engineered crops.

The major objective of agricultural biotechnology research in Egypt is the production of plant varieties that consume less water and that are higher yielding. It supports agricultural development through applied research with the goal of increasing food per unit area. Egypt seeks to rationalize water consumption systems and improve the properties of the soil.

The lack of an enacted biosafety law has led to promulgation of various decrees dealing with agricultural biotechnology. Oversight falls under purview of four different ministries; all count with representation on the National Biosafety Committee (which has not met since 2014).

The country requires a practical biosafety framework that adopts a clear policy. Without one, Egypt cannot move forward in the area of agricultural biotechnology.

The absence of a legal framework impedes field trials, innovation, as well as the commercial use of GE crops produced domestically by Egyptian scientists and researchers. Egypt is a party to the Cartagena Protocol on Biosafety (CPB).

1.2. India: Brief History of Patenting of Biotechnology in India (Intellectual Property India, 2013)

Biotechnology exploits biological materials, living or non-living, and is broadly classified as classical and modern biotechnology. The age-old fermentation process for producing alcohol, isolation of antibiotics from molds or other micro-organisms are only a few examples of classical biotechnology. Modern biotechnology started with the gene splicing technology or genetic engineering which developed in the late seventies of the last century. By using genetic engineering, many useful things like human insulin,

human growth factors, monoclonal antibodies, etc. have been developed. The biotechnological inventions therefore include products and/ or processes of gene engineering technologies, methods of producing organisms, methods of isolation of microorganisms from culture medium, methods of mutation, cultures, mutants, transformants, plasmids, processes for making monoclonal antibodies, cell lines for making monoclonal antibodies, etc. While on the one side, biotechnological inventions have resolved many problems and branched out to several fields, on the other side, they have invoked many debates.

The application of genetic engineering in plants and animals has resulted in exciting and yet debatable technological developments such as transgenic plants, animals and isolation of human genes for using them to produce medicaments. Scientists across the world are using bioinformatics tools, ingenious techniques and genomes of organisms to probe the mysteries of biological processes and the living world thereby generating vast amounts of information which may provide the keys to new medical treatments, improved crops and so on.

However, there are some issues relating to patentability of biotechnological inventions which are of serious concern to the users of Patent System such as novelty, obviousness, industrial applicability, extent of disclosure and clarity in claims. In addition, a few special issues have also evolved such as those relating to moral and ethical concerns, environmental safety, issues relating to patenting of ESTs (Expressed Sequence Tags) of partial gene sequences, cloning of farm animals, stem cells, gene diagnostics, etc.

Thus, the patenting of inventions in the field of biotechnology poses challenges to the applicants for patents as well as to the Patent Office. Therefore, there is an urgent need to put in place Guidelines to establish uniform and consistent practices in the examination of patent applications in the field of biotechnology and allied subjects under the Patents Act, 1970. Thus the guidelines are intended to help the examiners and controllers of the Patent Office so as to achieve uniformity and consistency.

Till 2002, as per the prevailing practice in the Patent Office, patents were not granted for inventions relating to (a) living entities of natural or artificial origin, (b) biological materials or other materials having replicating properties, (c) substances derived from such materials and (d) any processes for the production of living substances/entities including nucleic acids. However, patents could

be granted for processes of producing non-living substances by chemical processes, bioconversion and microbiological processes using micro-organisms or biological materials. For instance, claims for processes for the preparation of antibodies or proteins or vaccines consisting of non-living substances were allowable.

In 2002, the Hon'ble Calcutta High Court, in its decision in 'Dimminaco AG v. Controller of Patents and Designs', opened the doors for the grant of patents to inventions where the final product of the claimed process contained living microorganisms. The court concluded that a new and useful art or process is an invention, and where the end product (even if it contains living organism) is a new article, the process leading to its manufacture is an invention. The Dimminaco case was related to a process for the preparation of a live vaccine for protecting poultry against Bursitis infection.

The Controller of Patents had refused the application for grant of patent on the ground that the vaccine involved processing of certain microbial substances and contained gene sequence. The Controller had decided that the said claim was not patentable because the claimed process was only a natural process devoid of any manufacturing activity and the end-product contained living material. The Hon'ble High Court held that the word "manufacture" was not defined in the statute therefore, the dictionary meaning attributed to the word in the particular trade or business can be accepted if the end product is a commercial entity. The court further held that there was no statutory bar in the patent statute to accept a manner of manufacture as patentable even if the end product contained a living organism. The court asserted that one of the most common tests was the vendibility test. The said test would be satisfied if the invention resulted in the production of some vendible item or it improved or restored the former conditions of the vendible item or its effect was the preservation and prevention from deterioration of some vendible product. The court further stated that the vendible product meant something which could be passed on from one man to another upon transaction of purchase and sale. In other words, the product should be a commercial entity.

The subsequent major step, which further opened the arena of grant of patents in the field of biotechnology, was in the year 2002 when the Patents Act, 1970 was amended by the Patents (Amendment) Act, 2002 where biochemical, biotechnological and microbiological processes were included within the scope of chemical processes for the grant of patent. The definition of

"invention" was also changed to "any new product or process involving an inventive step and capable of industrial application" thereby deleting the word "manner of manufacture" as mentioned in the earlier Act. India joined the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure on 17th December 2001. Consequently, section 10 of the Act was amended in 2002 to provide for deposition of the 3 biological materials and its reference in the patent application in case the invention relates to a biological material which is not possible to be described in a sufficient manner and which is not available to the public.

The Patents Act, 1970 was amended by the Patents (Amendment) Act, 2005 paving the way for the grant of product patents in any field of technology including biotechnology with certain exceptions keeping in view the national policy to protect the public interest. The Act, as amended, recognizes the International Depository Authorities (IDAs) under the Budapest Treaty.

IPR in Pharmaceuticals and Agriculture in India (Rajya, S., 2021):

A- IPR in Pharmaceuticals Discovery of New Drugs:

1. Pharmaceutical industry is one of the prime beneficiaries of the IPR. The Committee was informed that three departments/ agencies are involved in managing the issue of IPR.

(i) Department of Pharmaceuticals, responsible for policy, planning, development and regulation of pharmaceuticals in the country. (ii) Central Drug Standard Control Organisation (Department of Health and Family Welfare) responsible for regulating the drugs, i.e. giving the approvals for manufacturing, marketing, maintaining the quality and safety of drugs; also provide license for marketing of drugs, both for global and domestic stakeholders. (iii) DPIIT which is looking after the IPR.

2. Indian Pharmaceutical Sector is third largest in volume at international level and is called the pharmacy of the world.

3. The Committee was informed about the number of patent application filed under Pharmaceuticals.

4. The Committee notes with concern that out of 16,134 patents filed during the last 5 years, only 4,345 were granted patents. The Committee recommends that necessary steps may be taken to expedite the process of examining/ granting patents.

5. The Committee noted that despite gaining technical expertise in reverse engineering, the manufacturing process of existing

medicines, India has gained prominence in global markets of generic medicine. It, however, learnt that drug discovery and innovation of new drugs still remains a big challenge to India. In this regard, the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers informed the Committee about the efforts in enhancing research and development of new drugs in India.

6. It was apprised by DoP that seven National Institutes of Pharmaceutical Education & Research (NIPERs) have been established in the country along with allocation of funds for enhancing research and development in drug discovery and development of new drugs. The Department has also proposed to set up three national centres of excellence for anti-viral drug discovery, medical devices, and for R&D in bulk drugs.

7. DoP further conveyed that based on the recommendations of 46th Report of the Departmental Parliamentary Standing Committee on Commerce, an inter-Departmental Committee (IDC) has been constituted to undertake cooperative efforts in areas of pharmaceuticals research which include periodic review and coordination of research work by various Governmental research organisations. DoP is also collaborating with NITI Aayog to devise Research & Development Policy for pharmaceuticals, medical devices and traditional medicines.

8. The Committee appreciates the initiatives of the Department of Pharmaceuticals in bolstering Research and Development activities in pharmaceuticals sector. The Committee acknowledges the fact that the research in generic segment of medicines as well as its successful patenting under Indian Acts has made India a strong generic player in the world. It, however, opines that for sustaining growth in global pharmaceutical market, research should be oriented towards niche segments and new drugs discovery. In this direction, joint research with global pharma players on discoveries of new molecules and compositions should be undertaken by the Department.

9. The Committee recommends that to encourage research and development in the Pharmaceutical Sector, policies for attracting investments from both the public and private sector may be explored by providing incentives such as tax rebate, reducing processing time and through industry academia partnership.

10. On a query by Committee on the research being conducted on indigenous pharmaceuticals including Ayurveda, DoP informed that all the seven National Institutes of Pharmaceutical Education and Research in India are already working on indigenous pharma

research such as Ayurvedic medicines, biopharmaceuticals, natural products, herbal drugs and traditional medicine. The endeavours being undertaken by DoP includes the following:- (i) Phytopharmaceutical Mission to promote development of phytopharmaceuticals in North East Region; (ii) An Inter-Ministerial Cooperation program of CSIR, DBT and ICMR on 'Phytopharmaceutical' drug development; (iii) A Turmeric Mission programme to generate high quality raw material for developing nutraceutical products and dietary supplements from turmeric as well as for developing curcuminoids or curcumin-based therapeutics for various disease segments; (iv) An Inter-Ministerial Cooperation between Department of Biotechnology and National Medicinal Plants Board (NMPB) under Ministry of AYUSH on biotechnological intervention in AYUSH sector; and (iv) A joint network programme between DoP and Ministry of AYUSH to develop plant-based therapeutics from indigenous medicinal plants to treat COVID-19 disease.

11. The Committee appreciates the endeavours being undertaken by the Department of Pharmaceuticals in the field of traditional and indigenous medicines which has become a potential thrust area in pharmaceuticals and drugs sector in wake of covid-19 pandemic. It recommends the Department to undertake an intensive research on AYUSH medicines and drugs including herbal remedies that would lead to advancement in availability of innovative drugs and medicines for treatment of novel diseases. Spurious Drugs.

12. The DoP informed that the Drugs and Cosmetics Act, 1940 and Drugs and Cosmetic rules, 1945 deals with import, manufacture, distribution and sale of drugs, cosmetics and notified medical devices in the country. As per the Act, Central Drugs Standard Control Organisation (CDSCO) is responsible for approval of drugs, conduct of clinical trials and in laying down the standards of drugs.

13. The Committee raised its concern on the rise in manufacturing of spurious and adulterated drugs in the country. In this regard, DoP informed that various measures are being taken by CDSCO to address the issue of spurious drugs and ensure the quality of drugs in the country. Since five years, the reforms are being undertaken by CDSCO in the drugs regulatory system which include strengthening of testing capacities of Central Drugs Testing Laboratories under CDSCO and amendments in the Drugs and Cosmetics Rules, 1945 to bring in stricter rules pertaining to manufacturing of pharmaceuticals such as submission of bioequivalence study when applying for

license of oral dosage form of certain drugs, joint inspection of manufacturing establishment by Drugs Inspectors of both Central and State Government, etc.

14. The Committee expresses its concern on the rising incidences of spurious and adulterated drugs in India which is not only a potential threat to the lives of its citizens but also dents its image as being one of the largest supplier of drugs and pharmaceuticals in the world. It, therefore, recommends the Government to roll out a track and trace mechanism at the earliest for the detection of authenticity and genuineness of medicines and medical devices from manufacturers to end users in supply chain.

B-IPR IN Agriculture:

1. Protection of IPRs in farming and cultivation sector, especially securing the plant breeding rights of farmers and farming innovations, is essential for the sustainable development of agriculture. In this regard, the Committee enquired Department of Agricultural Research and Education (DARE) about the measures of the Government to encourage and protect IPRs in the field of agriculture.

2. The Department informed the Committee that Indian Council of Agricultural Research (ICAR) is implementing guidelines for Intellectual Property Management and Technology Transfer/ Commercialization (IPMTT/C) in India including the policy framework for systematic management of IP available and created by researchers in ICAR institutes. An IPR Cell has also been created at ICAR for the purpose.

3. Also, a three-tier IP management mechanism in ICAR has been constituted and accordingly Institute Technology Management Units (ITMUs) have been established in all ICAR institutes in India to undertake initiatives pertaining to filing of IPRs generated in research work as per Indian legislations. It was further apprised that Agrinnovate India Limited, a registered Company of the Department of Agricultural Research and Education (DARE) deals with the commercialization of IPRs generated in agricultural research.

4. On a query of the Committee about awareness generation of IPRs amongst farmers, DARE informed that ICAR Agricultural Technology Application Research Institutes (ATARI) in cooperation with their Krishi Vigyan Kendras (KVKs) is making efforts to create awareness of Intellectual Property Rights (IPRs) amongst the

farmers. It was also informed that Protection of Plant Varieties and Farmers Rights (PPV&FR) Act, 2001 which became operational in the year 2007 has significant provisions to protect the farmers' interest and plant varieties. ATARIs and PPV&FR Authority have also jointly launched the programme for creation of awareness among the farmers and other stakeholders about the provision of PPV&FR Act.

5. The Committee was further informed that the grant of Plant Breeders Rights by PPV&FR authority has impacted the agricultural development by accelerating the agricultural development and to stimulate investment for research and development both in public and private sector for the development of new plant varieties. This protection facilitates the growth of the seed industry in the country which will ensure the availability of high quality seeds and planting materials to the farmers.

6. The Committee appreciates the supportive measures being undertaken by Indian Council of Agricultural Research (ICAR) in mobilizing agricultural researchers and scientists in the ambit of IPRs. It, however, notes that acculturation of Indian farmers and farming communities in IPRs is far from being achieved in India. In this direction, the Committee recommends that the Government should make all out efforts in creating awareness amongst farmers and farming communities so that they voluntarily embrace IPRs in protecting their rights in areas of farming innovations, breeding and varieties.

7. For disseminating information about the role of patent in agriculture, KVK (Krishi Vikas Kendras) can play a significant role as they work at block level and the farmers also consider them as local. Exclusive videos/ multimedia options/ bill boards may be used to create awareness. In this digital age, the videos in local language can be sent on their cell phones to upgrade their knowledge. 19.8 The Committee also recommends that more governmental efforts through legislation and implementation of law may be made in favor of farmers since they are not aware of the legal system and sometimes get trapped in IPR issues by private companies.

India has sailed through the journey from a state of a total lack of IP awareness to the present state of proactive pursuit of IP in frontier areas of technology. Having unleashed India's IT potential in the recent past, the time has now come to harness the tremendous strengths and energies of the countries in the Biotechnology Sector (Pati, A.K. and Sinha, A., 2014).

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1.3. Nigeria: Intellectual Property (IP) in Nigeria: Balancing Rights, Traditional Knowledge and Innovation in Developing Agricultural Biotechnology Systems:

Nigeria Traditional Knowledge, biotechnology and IPRs Traditional knowledge (TK) refers to a body of indigenous resources, which include techniques, information, animate and inanimate materials found in a somewhat exclusive nature to a community. Traditional Knowledge by its nature is a community property as its transmission is usually as a community cultural heritage. The issues of definition, ownership, and consequent rights are affected by the opaque scope of these resources. Commission on Intellectual Property Rights (2002) has documented the fact that livelihoods of indigenous peoples worldwide and the conservation of biodiversity depend on the preservation and protection of TK and that Indigenous peoples and rural communities have developed an intimate knowledge of the use and functioning of biological and natural resources over centuries of close dependence on these resources. For developing countries, like the developed countries before them, the development of indigenous technological capacity has proved to be a key determinant of economic growth and poverty reduction. This capacity determines the extent to which these countries can assimilate and apply foreign technology. Many studies have concluded that the most distinctive single factor determining the success of technology transfer is the early emergence of an indigenous technological capacity (Commission on Intellectual Property Rights, 2002). Traditional Knowledge is vital for life, health, food security and agriculture. It also forms the basis of cultural identity, contributing to social cohesiveness and thereby reducing vulnerability and poverty (Adisa, T.A. and Toro, I.A. 2017).

Waziri (2014) observed that there has now been discovered a need to preserve and protect Traditional Knowledge (TK) from misappropriation especially because of its nature: It is usually neither written down, nor registered with any government agencies. It exists and is usually used based on a principle of open sharing, such that it is very susceptible to being poached by bio-pirates, who then acquire IPRs over the knowledge and deny access to the actual innovators and/or custodians of the said knowledge. The situation is not helped by the fact that existing western intellectual property laws support, promote, and excuse the wholesale, uninvited appropriation of whatever TK promises profit, with no obligation or expectation to

allow the originators of the knowledge a say or a share in the proceeds.

Challenges of Implementing IPRs in Nigeria Nwokocah (2012) identified a number of challenges facing IPR s in Nigeria. These challenges while not specific to agricultural biotechnology are very much applicable to it in every respect. First, the administration of IPRs in Nigeria is incapacitated by inadequate skill and incompetence. People involved in its administration are usually not experts. Secondly, the infrastructure for operation of the IPR Nigeria is still largely underdeveloped. Thirdly, the piracy and counterfeiting have become an important factor frustrating business development in Nigeria. Fourthly, after decades of independence, Nigeria has not made any significant change in its IP laws. The laws have remained outdated.

Adekola and Eze (2015) in explaining the challenges arising from infringement of IPRs likened it to a car, which can be driven by only one person at a time, compared to an author who publishes a book which many people can read at the same time. They further stated that intellectual property is much easier to copy than to create. It may take many months of work to write a novel or computer program, but with a photocopy machine or computer, others could copy the work in a matter of seconds. Ineffective implementation of proprietary laws in Nigeria has made this scenario the experience of many scientists. Lack of basic infrastructure for detecting infringements has made tracking of rights protected research results or other innovations difficult. The result is that rewards that should make research attractive may not be fully enjoyed by scientists.

In view of the embryonic stage of the development of agricultural biotechnology in Nigeria and other developing agricultural systems, an unequalled opportunity presents itself for developing an Intellectual Rights system that ensures that the full benefits of innovation in this field is derived. It is also important to note that elements which sustain the innovation process, especially traditional knowledge and farming systems are not only preserved and protected but are engaged in through a sustainable resourcing process. This may hopefully assure the contribution of these developing agricultural systems in the evolution of a globally equitable agricultural system (Adisa, T.A. and Toro, I.A. 2017).

2. Protection of Intellectual Property Rights in the Biotechnological Fields: Developed Countries:

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2.1. Australia: The Australian Medical Biotechnology Industry and Access to Intellectual Property: Osues for Patent Law Development (Nicol, D. AND Nilesen, J., 2001 and Victoria, 2008).

Biotechnology companies face unique challenges for the following reasons: the research intensive nature of the industry: the massive increase in patent activity in the area of biotechnology; the preponderance of upstream patents with broad claims; the reliance of downstream companies on access to patented research tools and techniques. Challenges facing the emergent Australian industry may be particularly acute given first, the need for Australian biotechnology companies to seek foreign investment and alliances to fund research and expand into international markets. Secondly, access to essential research tools and technologies requires negotiation of a considerable number of license agreements with patent holders. This is complicated because the majority of biotechnology patents are held by non-Australian upstream companies and institutes. By entering into alliances, companies may find that their ability to acquire all the licenses they need to conduct their research is impeded. Although the Federal Government has put forward a number of initiatives to promote the establishment of a biotechnology industry in Australia, consideration of issues associated with access to intellectual property, particularly access to research tools and techniques. is notably absent. It is vital that these issues are canvassed by the federal government at an early stage of investment in the Australian biotechnology industry. A patent law regime in line with international obligations is essential in order to encourage innovation and investment in the industry. Yet this same regime may inhibit research and product development. The balance is a fine one and the very system that has as its primary purpose the reward of innovation. may in some instances have the obverse effect. It is unrealistic to assume that all impediments to the growth of the industry could be removed. However, it should be recognized that the existing balance may weigh too heavily against the industry as a whole. Further work is necessary to assess the imbalance and to investigate potential solutions. While it is desirable to consider changes to patent standards as a starting point, it is unlikely in the short term that the rules governing the grant of patents will change considerably. Broad upstream patents will continue to be granted and the validity of existing patents will remain unchallenged. It is more likely that resolutions will come from the legal framework for use of

patents, and there is certainly scope for further investigation in this area.

Biotechnology Patent Peculiarities:

Patent applications concerned with microorganisms Under Australian patent law, if an applicant chooses to claim a life-form-type invention, such as a microorganism, a virus, a cell line, a hybridoma, a complex polynucleotide or a complex polypeptide, then a full description of the life-form, together with the best method of performing the invention known to the applicant must be provided. Because of the complexity of biological systems, however, it may be difficult or impossible to describe an invention relating to such an invention fully in words, and independently obtaining a life-form from original source material is sometimes not one hundred percent repeatable. The Budapest Treaty provides a solution to the problem of sufficiently describing inventions concerning microorganisms, by allowing the deposit of a sample of the microorganism with an "International Depository Authority" which is recognized by contracting countries for the purposes of patent applications in treaty countries. Australia is a signatory and contracting country to the Budapest Treaty.

The Budapest Treaty:

Expert Solution Before the patent application is published; the applicant has the option to notify the Commissioner of Patents that the Budapest Treaty deposit should only be made available to other parties under restricted circumstances. This is termed the "Expert Solution", and is intended to prevent competitors gaining unfair commercial benefit from the deposited lifeform prior to the grant of a patent. Where the Expert Solution is requested by the patent applicant, before a patent is granted on that application, or before the application has lapsed or been withdrawn or refused, the Commissioner may only authorize release of a sample of the deposited microorganism following a request by a third party to a person who is a "skilled addressee" nominated by the third party, and who does not have an interest in the invention. This approach is intended to allow third parties to determine the nature of the invention, for example to determine whether they may infringe a patent if it is ultimately granted on the application, without directly having access to the deposited material.

2.2.USA:

a-Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture in USA (Clancy, M.S. and Moschini, G., 2017).

Formal protection for intellectual property arrived relatively late for agricultural (biological) innovations and has resulted in a diverse set of IPR forms. But the trend has clearly been one of strengthening and broadening of the scope of IPRs, in the United States and internationally. Because biological organisms such as plants can be easily reproduced and multiplied, lack of IPRs severely hinders innovators' ability to appropriate returns from their efforts. Insofar as such incentives are necessary, the trend towards strengthening of IPRs should be conducive to increased private research efforts.

The evolution of the seed industry, and the major expansion of agricultural R&D activities, is certainly consistent with this perspective. Indeed, stronger IPRs have been vigorously embraced by this industry and have contributed to a major transfer of breeding activities from public institutions to an increasingly concentrated private sector. Beyond R&D investments, there remains a shortage of empirical evidence that stronger IPRs have resulted in larger innovation gains. The literature on the impact of plant patents and PBRs on innovation using traditional breeding techniques provides mixed conclusions. GE technology, on the other hand, appears to have many characteristics that make it likely to respond to stronger IPRs. Whereas there is no direct measure of the impact of utility patents on plant innovation, some empirical evidence suggests that the use of GE technology has accelerated the rate of plant innovation for some crops. In any case, the agricultural literature seems consistent with the broader empirical work on IPRs and the rate of innovation, which indicates the effects tend to be heterogeneous by industry, and which is rather ambivalent as to the link between strong IPRs and the rate of innovation. It bears noting at this juncture, however, that the challenges inherent in trying to uncover causality in these settings are formidable.

It may be unreasonable to insist on weaving strong policy conclusions about IPRs on the available empirical evidence. Much attention about the strengthening of IPRs has been devoted to the concern that it may adversely affect innovation. Economic theory provides some reasons for apprehension, especially in cumulative innovation contexts relevant to plant innovation.

b-The Biotechnology Industry Organization (BIO) and USA (Wilson, S. F., 2015):

The Biotechnology Industry Organization (BIO):

The Biotechnology Industry Organization (BIO) appreciates the opportunity to participate in the Special 301 process and is hopeful that our contribution will assist the United States Trade Representative's (USTR) efforts in preserving strong intellectual property protections for United States' companies internationally. BIO appreciates the opportunity to comment on 2015 Special 301 Review: Identification of Countries under Section 182 of the Trade Act of 1974: Request for Public Comment and Announcement of Public Hearing. BIO is a non-profit organization with a membership of more than 1,000 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in almost all of the 50 States and a number of foreign countries. BIO's members research and develop health care, agricultural, industrial, and environmental biotechnology products. Our members have provided the information found in this submission and we have compiled the information in aggregate form. BIO has chosen to aggregate the issues to help identify roadblocks affecting U.S. biotechnology companies and to maintain the confidentiality of our member's responses. To this end, BIO has identified the following countries of interest and recommends the following for our 2013 Special 301 submission.

Priority Watch List: BIO requests USTR to place Argentina, Brazil, Canada, Chile, China, Ecuador, India, Indonesia, South Korea, Thailand, Turkey, and Venezuela on the Priority **Watch List:** Watch List: BIO requests USTR to place Australia, Colombia, Egypt, the European Union, Mexico, Paraguay, Peru, Philippines, Russia, and Vietnam on the Watch List. Section 306 Monitoring: BIO requests USTR to continue monitoring Paraguay under Section 306.

Finally, we hope our submission helps the U.S. government identify IPR roadblocks and potential solutions that will help increase U.S. exports and create jobs in the United States.

c- Recent BIO IP Publications:

Taking Stock: How Global Biotechnology Benefits from Intellectual Property Rights provides a survey of current economic academic literature regarding IP. The key findings include; a) A "growing body of evidence suggesting a positive link between economic development and growth, technology transfer, increased

rates of innovation and the strengthening of IPRs. This is particularly true in knowledge-intensive sectors such as biopharmaceuticals. b) "Much of the international debate on biopharmaceutical innovation focuses on downstream issues: whether IPRs stand in the way of commercialization and whether they enable or delay access to medicines in developing countries. This discussion is usually placed in the context of the "North-South" divide (i.e. developed vs. developing world) and the extent to which the use of IPRs benefits or damages developing countries." c) "The discussion on the use of IPRs in upstream innovation (or the relationship of IPRs and biotechnology innovation in the context of biotech SMEs and universities) is often theoretical in nature and only at times based on data and collected evidence. Some international debates on IPRs relating to the upstream R&D process also examine the issue of ownership of genetic innovations and biologic materials and so-called research exemptions." d) "Recent empirical studies and surveys seem to significantly ease ongoing concerns about the extent to which the patent system may be used in a manner that slows or hinders access to biotechnological research and innovation.

BIO also commissioned research to review the economic effects of university and nonprofit licensing of inventions in the United States. For the years 1996-2010 the study finds: a) Academic licensing contributed up to $836 billion in gross industry output, b) Contributed up to $388 billion to the GDP, c) And provided up to 3 million "person years of employment." Finally, BIO participated in two reports reviewing innovative models and approaches for providing health care in the developing and least developed world. Bringing Innovation to Neglected Disease Research and Development reviews the barriers to neglected disease research and product development. The second report, Case Studies for Global Health provides access to a database of innovative approaches to solve a global health challenge.

References:

1. Adekola, T.A. and Eze, S.E. Intellectual property rights in Nigeria: a critical examination of the Nigeria Copy Rights Commission in Journal of Law, policy and globalization: 2015; 35, 2015.
www.iiste.org/journals/index.php/JULP/article/download/20899/21200

2. Adisa, T.A. and Toro, I.A. Intellectual Property (IP) in Nigeria: Balancing Rights, Traditional Knowledge and Innovation in

Developing Agricultural Biotechnology Systems. Journal of Applied Information Science and Technology: 2017; 10 (2): 93-101.
3. Alam, E. A. Innovation and Recent Advancement in Green and Pharmaceutical Biotechnologies in Favor of Drug Industries: 2022. ISBN. 978-977-94-0464-6.
4. Ban, J. Agricultural Biological Warfare: An overview". The Arena: 2000; Number 9, June, pp. 8, Washington: Chemical and Biological Arms Control Institute.
5. Clancy, M.S. and Moschini, G. Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture. Annual Review of Resource Economics: 2017; 9. DOI: 10.1146/annurev-resource100516-053524.
6. DaSilva, E. J.; Baydoun, E. and Badran, A. Biotechnology and the developing world. Electronic Journal of Biotechnology: 2002; 5 (1): 1-29.
7. Intellectual Property India. Office of the Controller General of Patents, Designs and Trademarks. Guidelines for Examination of Biotechnology Applications for Patent: March 2013.
8. Malik, K. and Yusuf, Z. Intellectual Property Rights in Plant Intellectual Property Rights in Plant Biotechnology: A Contribution to Crop Biosecurity. Asian Biotechnology and Development Review: 2005; 8 (1): 7-43.
9. Nicol, D. AND Nilesen, J. The Australian Medical Biotechnology Industry and Access to Intellectual Property: Issues for Patent Law Development: Sydney Law Review: 2001; 33: 347-374.
10. Nwogu, M. I. O. The Role of Nigerian Patents Law in Biotechnology Transfer, Journal of Law, Policy and Globalization : 2014; 31, 2014. Pg. 121- 125.
11. Nwokoach U. Nigerian intellectual property; overview of developments and practices. NIALS Journal of Intellectual Property (NJIP): 2012 www.nials-nigeria.org/journals /uche%20Nwokocha-NJIP%202.pdf.
12. Pati, A.K. and Sinha, A. Biotechnology and IPR: The Importance of Patent in the Indian Perspective. Law Mantra: 2014; 2 (8).
13. Prasad , R., Bagde, U. S. and Varma, A. An overview of intellectual property rights in relation to agricultural biotechnology. African Journal of Biotechnology: 2012; 11(73): 13746-13752.
14. Rajya, S., Review of the Intellectual Property Rights Regime in India. Department Related Parliamentary Standing Committee on

Commerce. One Hundred And Sixty First Report. Rajya Sabha Secretariat, New Delhi July, 2021/ Shravana, 1943 (Saka), India.
15. Sakr, M. Experience of Egypt in technology transfer and IPR management. Expert Group Meeting on Intellectual Property Systems in the Arab Region. Beirut, Lebanon, 17-18 April 2019: 1-45.
16. Victoria. Biotechnology Intellectual Property Management Manual. Spruson & Ferguson. ISBN 978-0-646-50349-3. 2008: 89-92.
17. Wally, A. Egypt Needs a Biosafety Framework for Agricultural Biotechnology. Agricultural Biotechnology Annual 2018. USDA Foreign Agricultural Services. Global Agricultural Information Network. GAIN Report Number: EG18023. Date: 10/11/2018: 1-13.
18. Waziri K.M. and Folasade A. O. Protection of Traditional Knowledge in Nigeria: Breaking the Barriers. Journal of Law, Policy and Globalization: 2014. www.iita.org/c/document_library/get_file?uuid=d4a582e1-9b33-431d-b7b1- 617b4189c056&groupId=2535.
19. Wilson, S. F. Biotechnology Industry Organization, Washington, D.C., USA: 2015; 2015 Special 301 Submission: 3-7.