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Role of IPR in Life Science industries

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Abstract— The rising tide of inventions in life science companies have kindled the need for the protection of high-value intellectual property as there is relatively substantial investment of time, mental labour and economic resources. The protection of IP in life sciences has always been a contentious matter as the inventions impinge on matters pertaining to the ethics, policies, public interest and socio-economic factors. Thence, this paper will illuminate the inter-relationship between the intellectual property rights and life science industries by drawing a nexus between Intellectual Property Rights AND bioinformatics, biotechnology, biopharmaceuticals and nanotechnology. Forbye, it will substantiate why/why not the innovations in life science corporations must be safeguarded.

Keywords: ***Bioinformatics, Biopharmaceuticals, Biotechnology, Copyright, Intellectual Property Nanotechnology, Rights, Plant Variety Rights, Patent, Trademark, Trade Secret.***

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I. INTRODUCTION

Intellectual property particularizes to the creations of human intellect which has been globally recognised in today's economy. Intellectual Property Rights are reckoned to be the cornerstone of any economy and their origination and protection is crucial for protracted development of a nation state. Currently, the intellectual property rights are not only being used as an instrument to protect the creativity and engender revenue but also to construct strategic alliances for the technological and socio-economic advancement. Knowledge and ideas are progressively significant element of trade. Most of the value of pristine medicines and other high technology commodities inheres in the amount of innovation, design, testing, invention and research involved. Online services, Computer software, books, films and music recordings are purchased and vended because of the creativity and information they encompass, not typically because of the paper, plastic or metal utilized to fabricate them. The merchandises that used to be traded as low-technology commodities or products now embody a lofty fraction of design and invention in their value. For instance, novel diversity of plants or brand-named apparel. Pioneers can be given the privilege to avert others from making use of their innovations, designs or other creations and to use that right to negotiate payment in return for others utilizing them. These are "intellectual property rights". The IPR covers copyright and related rights (i.e. the rights of performers, producers of sound recordings and broadcasting organizations); industrial designs; geographical indications including appellations of origin; trademarks including service marks; patents including the protection of new varieties of plants; the layout-designs of integrated circuits; and undisclosed information including trade secrets and test data. The innovators are proffered these prerogatives as an incentive to create ideas and inventions which will be beneficial for the society [1]. The protection of the intellectual property is one of the prime factors for the economic growth and elevation in the technological domain as it impels innovation and development in the competitive society.

The life sciences have augmented in all the domains of technology, precipitating to the creation of one of the most convoluted systems of our time. The life sciences subject is no longer a stand-alone discipline; it is a dynamic high-octane domain that is rapidly evolving and integrating with other disciplines, which has given leap to a proliferating list of interdisciplinary fields such as nanotechnology, bioinformatics, biopharmaceuticals and biotechnology. In general, innovations in life sciences corporations entail a relatively substantial investment of time and economic resources. Investment of such nature triggers efficacious creation and protection of high-value intellectual property. This is indispensable for spellbinding the strategic partners and investors, which is pivotal for the subsistence and advancement of life sciences corporations, precisely small and medium-sized enterprises. In India, the protection of intellectual property in life sciences has always been a debatable issue, whether it is with regards to the application of traditional knowledge, biological resources, Bacillus thuringiensis technology or pharmaceuticals. This is because the innovations in life sciences impinge on matters pertaining to the socio-economic factors, public interest, ethics and policies. Aside from dealing with the intrinsic risks and uncertainties related with product development and garnering commercial gains, innovations in life sciences are frequently

faced with the challenge of crucial requisite for the professionals who can recognize, comprehend and constructively navigate the convoluted web of statutory, regulatory, ethical, social and commercial desiderata for the protection and promotion of the intellectual property. Another significant concern for life sciences corporations is that the patent protection regarding the related technology and invention is notably pregnable to impairment by slight tweaking. The invention or technology associated to the life sciences domain typically entails more time for technology transfer because of stringent and complex legal compliances pertaining the safety of technology or invention. These matters would ultimately affect the efficacious lifespan of the technology or cognate product developed at the cost of huge investment and would decrease the potential of recuperating commercial benefits [2].

II. BIOINFORMATICS AND INTELLECTUAL PROPERTY RIGHTS

Bioinformatics is the science of generation, transference, receipt and deciphering of information in the biological systems. It is the accumulation, storage, categorization, and analysis of biological and biochemical information plying computers, applying to genomics. It has been contributing significantly towards the areas of agriculture, pharmaceuticals, medicine and drugs [3]. Bioinformatics is the convergence of computational and analytical instruments with the discipline of biological research. It is the employment of computer to the administration of biological information. Computer technology is utilized to accumulate, stock, examine and amalgamate genetic and biological information which can thereafter be employed to the gene-based drug discovery and development. Bioinformatics has emanated as a pristine area to manage the biological data by employing information technology contrivances so that fruitful reverberations could be yielded. Bioinformatics software and databases embody information carrying great prospective for medical research [4].

In the contemporary IT aeon, bioinformatics is sprouting and burgeoning swiftly due to the vigorous database systems accessible and the increasing and vast proportion of the biological data published. Bioinformatics database is an integrated corollary of biotechnology and information technology and plays an indispensable part in revitalizing modern life science research [5].

IP protection for bioinformatics databases plays a vital role in bolstering progress of biotechnological industry and biological sciences. The proliferating investments in the bioinformatics area have mushroomed the necessity of apposite intellectual property laws. This is one of the chief dimensions in any emerging tract [6]. Contemporaneous, in most nations, bioinformatics databases are safeguarded by the subsisting intellectual property laws.

Bioinformatics, which is the blending of molecular biology with computer science, is crucial to the use of genomic information in comprehending human maladies and in the recognition of novel molecular targets for drug discovery. Bioinformatics entail the design and application of systems and programs for the storage, administration and anatomization of huge quantities of DNA sequence data. Such roles necessitate profound relational and programming database adroitness, that extremely few biologists hold, and hence it is chiefly the computational professionals who are filling these positions. Bioinformatics encompasses the acquisition, storage, organization, visualization and analysis of information embodied within biological molecules. In order to be a patentable subject matter, an innovation should be a machine, manufacture, process, or composition of matter or any improvement. Bioinformatics is anatomized as per the following categorization: (a) Biological sequences such as DNA, RNA, and protein sequences, (b) Databases in which these sequences are systematized, and (c) Software and hardware contrived to generate, access, systematize, and anatomize information comprised within these sequences and databases.

III. PATENTS

Entrepreneurs and corporations can procure a legal monopoly to safeguard their technology from being produced and vended by adversaries, hence making patents a crucial impetus for technology innovation and development. Utility patent is usually related with bioinformatics innovations and can be procured for useful and new, non-obvious process, manufacture, machine, composition of matter, or novel and useful refinement of any of the aforementioned.

IV. COPYRIGHTS

It can be utilized to safeguard bioinformatics related stuffs such as scientific books, articles, manuals, software code, compilations of facts/databases, web pages, multimedia works and graphic artwork. Trade Secrets: It is utilized to safeguard bioinformatics related stuffs such as software code, formulas, compilations of facts/databases, manuals and processes [7].

V. BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS

Generally, biotechnology is elucidated as “the employment of science and technology to living creatures, as well parts, models and products thereof, to reorient living or non-living matters for the production of goods, services and knowledge” [8]. Currently, the IP protection for biotechnology is in a state of flux. While earlier the living creatures were primarily disbarred from protection, outlooks are now transmuting, and biotechnology is progressively undergoing some form of protection. These modifications have generally taken place in the United States and other industrialized nations, but as other nations tend to vie in the new biotechnological marts, they are plausible to tweak their national legislations to safeguard and invigorate investment in biotechnology. Currently, there are two prime systems of protection for biotechnology: rights in plant varieties, and patents [9].

VI. RIGHTS IN PLANT VARIETIES

Plant Variety Rights are globally recognised type of intellectual property used to safeguard idiosyncratic plant varieties. The exertion of Plant Variety Rights is homogeneous in proposition to the IP protection propounded

through copyright on music and books and to patents on a vast variety of inventive creations embracing biological material. The Plant Variety Rights drops protection and inspirits further invention in plant breeding. This system permits plant breeders to amass royalties on the production and vending of seed of their protected varieties [10]. The PVR protection underpins access to quality seed of proven high-performing plant varieties by means of a dedicated mechanism of invention, investment and independent evaluation [11].

Grant of PVR furnishes certain exclusive prerogatives on the holder, encompassing the exclusive privilege to vend the reproductive material (e.g. whole plants, cuttings, seeds) of the protected variety. Nevertheless, the prerogatives do not elongate to consumption material (e.g. wheat seed grown for milling flour, fruit). Notably the exclusive rights explicate what others may or may not do in correspondence to the protected varieties [12].

Plant variety protection is imperative because buoyant breeding necessitate substantial knowledge and prowess. Additionally, large-scale breeding requires scientific & proficient manpower, specialized equipment (for example, greenhouses, growth chambers and laboratories) and considerable investment in land. It takes a prolong duration to burgeon a successful plant variety (10-15 years in the case of many plant species). However, not all novel plant varieties are successful and, even where the varieties show appreciable ameliorations, alterations in mart desiderata may obliterate the likelihood of a return on investment. Hence, it is indispensable to equipoise the benefits with the return of the original high investment. Usually, though, plant breeding upshots in the availability of varieties with upsurge yield and ameliorated quality for the interest of the society. The long-term and sustained breeding attempts are only fruitful if there is a prospect to be guerdoned for the investment made. To recuperate the expenses of this research and development, the breeder may seek protection to procure exclusive entitlements for the pristine variety. Concomitantly, a new variety, once let out, can frequently be deftly reproduced by others. Thus, the original breeder is divested of the equitable opportunity to benefit from his or her investment. Therefore, it is crucial to lay out a constructive structure of plant variety protection, which vitalizes the progression of new plant varieties consequently uplifting the breeder and society [13].

VII. PATENTS FOR BIOTECHNOLOGY

A patent, which is a form of industrial property can defined as an exclusive right granted to the person (patentee/ patent holder) who has invented a novel or useful product/ process or has made an improvement to the existing product or the new process of making the product. Patents are generally granted over all types of inventions including the inventions in the field of information technology, chemical, mechanical engineering, pharmaceutical and biotechnology. Although the plant and animal varieties or crucial biological processes for the production of plants and animals (apart from microbiological processes or their products) are not contemplated as inventions, and thus, they are excluded from being patented. But in practice, certain patentable claims on plants, animals, the traditional knowledge based on plants and the claims over the protection of plant varieties are made. The issuance of patents over the living organisms has created an ethical dilemma all over the globe. The patenting of the life forms, medicines, stem cells, traditional knowledge (biopiracy) has jiggled the planet.

In order to obtain a patent in any system, the patent holder is required to satisfy the triple test of patentability criteria that involves the test of novelty, non-obviousness and usefulness. The patentable inventions can be pondered as both useful and detrimental at the same time. For an instance, the Harvard' OncoMouse was the first mammal to be patented which was developed to be used in cancer research. Biotechnology patents raises moral implications and complex issues globally. Patents not only act as a roadblock for the new entrants but also hinder the process of free use and exchange of biological materials between the communities. Although, it has been said that patent encourages innovation but in reality, it obstructs the scope of new inventions as it grants an exclusive right to the patentee to block others from entering into the related field. Also, there exits the problem of different intellectual property laws in different countries that is to say what is protected in one country may not be considered relevant to be protected in other country. Hence, the lack of uniformity in patent system at global level often leads to major controversies.

A biotechnological patent is a monopoly right that is granted to the patentee in the field of biology to exclude others for a limited duration of time (20 years) from making, using, exercising and vending his invention. Biotechnology usually involves the use of biological materials, living or non-living organisms and is broadly classified into classical and modern biotechnology. Classical biotechnology involves the processes that are based on the ability of the biological agents or microbes to conduct a reaction that generates a product. Examples- conversion of milk into curd, yeast clones, fermentation that involves the use of microbes to make food and beverages. Whereas the modern biotechnology involves the scientific use of the living organisms in whole or their parts such as molecules, cells, tissues or organs. Examples- recombinant DNA technology, transgenic organisms, GM crops, bioremediation, monoclonal antibodies (mAb) which is used for the treatment of cancers, Polymerase Chain Reaction technology which is used in molecular biology in order to intensify a single or few copies of DNA and stem cell research. Patents are granted in order to safeguard the interest of the patent holder with an object to encourage scientific research, stimulate new innovations of commercial utility and boost industrial progress. But the patents on biotechnological inventions commodify life-forms and they grant an exclusive right to the patent holder to exploit their invention and further restricting the research process. India is one of the bio-diversity rich countries, so it thus becomes prudent to provide protection to the bio-resources and not to grant patents on the life-forms on the basis of the principle of morality.

As per the opponents: In India, animals and plants are considered to be sacred so patenting of any animals, plants or any other life form would be a desecration. Indeed, biotechnological inventions do provide potential benefits to

the society and the patent holder should be rewarded for his work but that does not mean to give the ownership or control of living organisms to the patentee. Till date no patent on living organism has been granted in India. By virtue of TRIPS agreement, India did provide patent on microbes and any other living invention that is produced through any biotechnological or microbiological process. The patent law is against the competition law as the patent law gives a monopoly right to the patentee to exclude others from making, using or exercising his invention which blocks the entry for new innovators to come up with their research and thus restricts the competition. Whereas, according to the proponents: The moral concerns pop up when a patent is granted over a living organism but in actuality lot of plants and animals are cut down and killed to satisfy human wants and whims. The innovators should definitely be rewarded for their mental labour and capital investment put forward by them. And hence, by granting a monopoly right to them that too for a short duration is just and fair. Therefore, "biotechnology patents must be regulated and not prevented."[14].

VIII. BIOPHARMACEUTICALS AND INTELLECTUAL PROPERTY RIGHTS

The pharmaceutical sector has an exceptional pre-eminence in wrangles about intellectual property policy and has served as the front line for domestic and global dissensions about the link between R&D incentives, intellectual property rights, cost and access to medicines. In most economies, the pharmaceutical sector is highly regulated and complex. Generally, the intellectual property rights have two primary sections of effect in pharmaceuticals. Firstly, there is the concern pertaining to pricing and access, where discourse pivots on the relatedness between intellectual property rights (especially patent rights), elimination of adversaries and the pricing and availability of new medicines. Secondly, there is the concern with regards to the R&D incentives-i.e., the role of intellectual property rights in proffering incentives to discover, develop and market novel drugs- and the outcome of IP rights on R&D outlay and its allotment across diseases, organizations and nations. The above-mentioned matters are closely associated, and their interplay put up a chain of extremely difficult political questions and economic issues [15].

Drug corporations are in the innovation business. They make use of the patents to safeguard their investment and avert competition for as long as possible plus they engage in developing novel and better drugs. Although, the corporations are working hard utilizing patents to safeguard their inventions from biosimilar or generic competition, from a business vista, the end of patent protections can considerably and negatively affect a corporation's bottom line.

Effective intellectual property systems and IP protections are crucial for ensuring that biopharmaceutical corporations can pursue the R&D that call forth the discovery of tomorrow's lifesaving and life-changing new medicines. IP systems vary from nation to nation. Countries like Japan, the United States, and some European countries enjoy modern, strong approaches to IP that invigorate invention and investment. Notwithstanding, many nations like India, China, and Canada, subsume intellectual property systems that discourage medical invention by not proffering enough protections, eventually decreasing patient access to new cures and treatment. Ergo, IP is the mainstay on which the progression of new cures and treatments is constructed. Intellectual property is crucial for revamping patient care, reinforcing an innovation economy and galvanizing economic growth. In the absence of the protection of a modern, strong intellectual property system, researchers may not have the ability to check out pristine areas of medical invention and excavate the discovery that will create the cures and treatment of tomorrow [16].

But it is to be noted that we are in an epoch where many extrapolate that "information wants to be free," and consequently, there have been lawsuits and efforts to incapacitate intellectual property rights [17]. The prevailing state of pharmaceutical industry connotes that intellectual property rights are being unjustifiably bolstered and exploited at the expense of consumer welfare and competition. The dearth of innovation and risk on the part of the drug industry underscores the partisanship that is prevailing at the cost of public good.

One of the enablers of alteration was the US Supreme Court's judgment in Diamond v. Chakrabarty (1980). Emphasizing on genetically modified organisms utilized in the petrochemical industry, the Apex Court's decision permitted genetically altered cells and their products to be patented. This ruling pave the way for new biotechnology patents and products, allowing advancement of the foremost biopharma blockbuster drugs. Consequently, biotechnology has budged far beyond its roots in genetically modified organisms, with novel therapies based on personalized medicine and genomics. Scientific advancement challenge creator to reinforce stratagems to safeguard invention that took them millions of dollars and years to develop, and the legislative and judicial system to make sure that the finest treatments are available to patients. Adjoining to the hassle are the requirement of value-based medicine and the call to decrease drug costs, which are driving biosimilars progression. Concurrently, the drift to augmented outsourcing and collaborative R&D can entangle licensing, escalating questions of IP ownership and the necessity to safeguard trade secrets [18].

The competition in the international pharmaceutical industry is spurred by scientific knowledge instead of manufacturing know-how and a corporation's prosperity will be chiefly contingent on its R&D efforts. Thus, investments in R&D in the drug industry are extremely high as a percentage of gross sales. One of the crucial concerns in this industry is the management of inventive risks whilst one aspires to obtain a competitive edge over rival corporations. There is high cost ascribed to the risk of breakdown in pharmaceutical R&D with the progression of potential medicines that are inadequate to meet the stiff safety benchmarks, being terminated, occasionally after many years of investment. For the medicines that do clear development snags, it takes about 8-10 years from the time when the compound was first synthesized. It costs hefty for bringing up a novel drug into the mart with all associated perils at the developmental phase, no corporation will like to risk its

intellectual property becoming a public property without enough returns [19].

IX. NANOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS

Nanoscience studies biological attributes of substances at the nanoscale. Nanotechnology functions at an immensely compact scale, as it utilizes the dimension of a so-called nanoscale, which is roughly between 1 and 100 nanometers, or 1 to 100 billionths of a meter. Nanotechnology research burgeons ameliorated systems, devices, materials and therapeutics.

Herein, for nanotechnology, all the subject matter can be potentially safeguarded under patent rights. The procedure of procuring a patent can be extravagant and may take a handful of years. Notwithstanding the cognate inflated cost and convolution, patents proffer the sturdiest protection for nanotechnology innovations as it permits the patentee to perpetuate a monopoly on the innovative conceptualization. Patent right is only safeguarded by the nation where the patent is filed. In order to procure protection in one or more nations, distinct applications by dint of the patent office of the respective nation must be done. The intercontinental nanotechnology advancements and applications have made foreign patent prosecution a significant facet in trade and legal considerations. The definition of novelty in each nation can be divergent, and the grace period may differ in other nations.

Trade secret, if diligently perpetuated, is an economical manner to safeguard intellectual property that is not patented but should not be divulged for numerous rationales. That is momentous to any nanotechnology corporation and is predominantly precious for start-ups, who may be at the phase of prioritizing the marts to encompass and are yet to set their corresponding patent strategy. Copyright, trademark, and mask work can be tremendously efficacious for nanotechnology corporations in certain circumstances [20]. The WTO's Agreement on Trade-Related Intellectual Property Rights provides the universal framework for intellectual property protection of nanotechnology innovations, especially patent protection.

The TRIPS Agreement propels member nations to make patents available for innovations in all spheres of technology subject to standard patent benchmark. Since additional nanomaterials and nanotechnology-enabled products percolate global trade, an international governance gap is emanating with regards to the safety, health and environmental regulation. The only considerable issue that the TRIPS left undetermined was the exhaustion of patent and other intellectual property rights. International exhaustion implies that, as early as an innovation is placed on the mart of any WTO member nation by the patentee with his assent, the patent can no longer obstruct the importation of the invention in any other WTO nation. Whilst this framework places a curtailment on market forces for some duration, it proffers magnificent pecuniary welfare benefits for society than it would in the absence of the grant of such monopoly [21].

Whilst innovations in the nanotechnology domain, subject to the fulfilment of the pertinent stipulations of patentability, would appear to qualify for patent protection but there are a quite a few matters that may require additional rumination, encompassing for instance the following:

- Nanomaterials can be safeguarded for their IP rights by inventors. Nevertheless, due to the interdisciplinary nature of nanotechnology, there is a peril of overlapping patent claims and dearth of divergence between traditional and nano-based patents [22].
- With reference to the general stipulations of patentability, a dubiety may ensue as to whether the replication of a known structure or product at an atomic scale would encounter the desiderata of novelty or, more significantly, inventive step.
- The granted claims are excessively wide, due at least in part to a lack of available prior art, which could permit patentee to lock up enormous sections of technology. In this backdrop, there is again a discerned peril of overlapping patents.
- The question of whether the prerogatives of a patent provided on a product without specification of the size of the innovation could either be regarded infringed by the corresponding nanotechnology innovation or form the foundation for soliciting royalties from the pioneer of that innovation [23].

X. CONCLUSION

In today's technology-driven age, the protection of Intellectual Property Rights is indispensable. IP is a life science corporation's most treasured resource, and its protection is essential to the company's future success. Every human endeavour which fosters scientific, economic, cultural and social development of society must be promoted and the innovator must be suitably rewarded by bestowing legal protection of his intellectual creation by taking public interest and socio-economic factors into consideration.

CONFLICT OF INTEREST

Authors declared that there is no conflict of interest in them.

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