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Comparative Analysis of Human Gene Patenting Policies

Abstract: In today's world more and more basic and applied researchers, indeed, see themselves on top of a colossal pyramid peeking from behind a faceless crowd of researchers in similar circumstances. Furthermore, the pyramid can stride-forward onto an unequaled heights than it would be possible to a single person that too as the base would be wide and firm. But what if one has to climb up the pyramid to put next block on the top and the researcher is required to obtain agreement of people before each newly placed block who previously put blocks in the pyramid and perhaps pay a royalty or tax to get such permission? If this system of intellectual property is employed, will the construction of the pyramid become a snail pace or will it become limited in the aspect of height?

Keywords: R&D; patent; WTO; DNA.

No doubt about it, innovations in the form of R&D, especially in the fundamentals of research, are today taking place at a spectacular pace, so there is no reason either to sound the alarm, particularly where credit most of the time manifests itself in a citation. When we evolve from the area of pure R to applied R and then D, we have every reason to be thinking whether the institutions in place (at the legal and commercial levels) are indeed suitably oriented towards the goal of incentivizing the development of new products and services that use numerous strands of innovations and thereby risk becoming buttressed by multiple patent holders. Thus, to finish the analogy, provisioning patents take over the function of the pyramid's building blocks [1, p. 120].

However, combining different metaphors thoughtful observers are more and more anxious that USA is in fact building a patent thicket, a dense net of overlapping intellectual property rights that a company has to slash through in order to actually commercialize a new technology. Through increasing innovation as well as multiple blocking patents, stronger patent rights may create the unintended effect of chilling, rather than promoting innovation.

The method of creating prior policies related to patenting a gene or a device falls beyond the scope of the current report, however, which leads to the appearance of sections concentrating on the genetic tests that shall be provided. With this scope, the studies were conducted by the Nuffield Council on Bioethics (a group in the United Kingdom), the Australian Law Reform Commission (ALRC), NRC, and the Organization for Economic Co-operation and Development (OECD). Moreover, FTC of the United States released a report on a patent policy that touched this issue as well as biotechnology.

Among other things, the SACGHS examined the gene patents of other countries which enables them to determine those that permit gene patents. It also allowed them to get an insight into

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how these countries have responded to issues that arise because of gene patents especially how these patents affect patient access to genetic tests.

An OECD report indicates that gene molecules can be patented in all OECD countries. While there's ongoing public debate about whether patents should be granted for DNA and other nucleotide sequences, the stance of official patent authorities in OECD nations has remained relatively consistent. As long as a DNA sequence is deemed novel and meets other patentability criteria like utility and inventiveness, it can be patented. Specifically, patents are granted for the molecule with the specified sequence and function, rather than the sequence as abstract information.

Furthermore, a European Union Directive from 1998 mandates that all member states of the European Union (EU) incorporate gene patenting into their respective national patent legislation. When Germany incorporated the EU directive into its national law, it additionally decided that a patent for a gene molecule would be limited to the industrial applications which are disclosed in the patent. France has a comparable provision within its patent legislation. This norm could imply that researchers are not obliged to obtain licensing agreements to conduct research on the genes that are patented. Also, anyone can patent the particular application of the gene if another scientist solves the problem. The doubtful legal status of a patented gene used for the diagnostic purposes and other research without a license hinders effective implementations of new diagnostic test. Committee covers neither the art of German and French law to this problem nor any articles that address this particular question.

According to the German policy analyst, Ingrid Schneider, Germany and France claimed that such patents were overcompensating and were "superstrict", and therefore, the generation of new knowledge would be stifled, and would also be economically unfavourable. Additionally, a lack of incentives for the researchers working in the downstream will also be created [2, p. 3].

France has also enacted legislation allowing the government to authorize compulsory licenses for patents safeguarding diagnostic techniques, devices, and products. Similar to France, Belgium, in compliance with the EU directive, introduced measures aimed at alleviating the potential adverse impacts of biotechnological innovations on healthcare. One aspect is a broadened research exception, clarifying that the rights of a patent holder do not encompass research involving or related to the subject matter of the invention. The extent of this research exception surpasses that of other European nations, which only allow research specifically on a patented invention. Another provision in Belgium permits the government to issue non-exclusive compulsory licenses for public health purposes to patents objects like in the case of French legislation. Further, Geertrui Van Overwalle and Esther van Zimmeren state that this particular provision may have been inspired by the restrictive licensing approach of the company Myriad Genetics that had been refusing to grant reasonable licenses to laboratories and hospitals that conducted genetic testing. These compulsory license provisions, however, are wider-ranging as compared to the U.S.’s march-in rights under the Bayh-Dole act because they apply to patents that arise from privately funded research, as opposed to patents after either a complete or partial government funding of research [3, p. 43].

Nations within the World Trade Organization (WTO), including the United States, are not entirely free to set their patent laws without limitations. They are obligated to provide at least the minimum patent protection specified in the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Hence, a question raised during Committee discussions was whether any legal alterations impacting the patent eligibility or enforceability of genes and associations would conflict with the U.S.'s obligations under TRIPS.

The Committee concluded that there is no reason for alarm, as the Agreement provides sufficient authority to endorse alterations facilitating access to and research on genetic testing. Firstly, countries have the option to exclude diagnostic methods for treating humans, plants, and animals other than microorganisms from patentability. They can also omit the inventions prevention of whose commercial exploitation within their jurisdiction is essential to safeguard public order or morality, including to safeguard human health, as stated in the section 2 of the article 27 of the TRIPS. Therefore, it seems that more extensive measures than those proposed here, specifically, excluding genes or diagnoses derived from genotype-phenotype associations from patent eligibility, would align with TRIPS.

Secondly, TRIPS allows member states to determine their own criteria for defining what qualifies as an invention. Following this principle, Argentina, Bolivia, Brazil, Colombia, Ecuador, Peru, and Venezuela have opted to categorize isolated gene molecules as discoveries rather than inventions. Finally, in case the conclusion is arrived that basic interactions are not protected this will not break the TRIPS Agreement no more than the exclusion of software and diagnostics made by the European Patent Convention.

Article 30 of the TRIPS treaty is the last provision that permits members to provide for limited exceptions to the monopoly rights issued by a patent, unless such easements clearly conflict with the normal exploitation of a patent by the patent owner. It can cause an unreasonable prejudice to owner, taking into account the interest of third parties.

Certainly, this provision was subject to a rather restrictive interpretation in the sole WTO case where the Agreement was scrutinized regarding a healthcare-related measure, namely Canada– Patent Protection of Pharmaceutical Products. In that instance, a panel for dispute resolution determined that the terms in Article 30 must be considered together, necessitating the respondent nation to provide justification for an exception under each clause independently. Moreover, the measure in question was assessed separately under Article 27 of the TRIPS Agreement, which mandates members to offer patents for any inventions in all fields of technology.

Canada-Pharmaceuticals was, however, adjudicated by a WTO panel, which functions as the trial court within the WTO system. The Appellate Body, akin to the WTO's Supreme Court, has not yet addressed any of the exemption provisions outlined in the TRIPS Agreement [4, p.86].

The fact that this case has been decided before the Doha Round of WTO negotiation is more crucial. In that Round, we saw a Ministerial Declaration where TRIPS interpretation was "to be in line with public health aspirations." Moreover, the TRIPS itself was reinterpreted through the Declaration on TRIPS and Public Health, which noted that even the TRIPS Agreement was not intended to, and should not, impede members from taking public health measures. Therefore, underlining our intention to stick to the TRIPS Agreement, it is expresses the view that the Agreement has to be interpreted and implemented in a way that is supportive of WTO members' rights to protect public health.

The Declaration further stated that they reasserted the entitlement of WTO members to fully utilize the provisions within the TRIPS Agreement, which offer flexibility for this objective. According to Alison Heath, the Declaration might imply that a dispute concerning a gene patent measure pointed at enhancing healthcare access will be approached with some degree of flexibility.

Issues of right are posed whenever the braiding of biotechnology and the intellectual property is introduced long-term researcher into the work of legislatures and society. Intellectual property laws that would work in the information age cannot be built on those, which were founded in indus-

trial era. In the given age of modern biotechnological inventions this particularly concerning genetic inventions, that cannot be categorized under the conventional areas of patent filing, i.e. chemicals and mechanics, are a novelty. Particularly with the evolution of human genomics and success in the Human Genome Project, gene turns out to have something to say because of the nature of the information that is carried rather than the physical quality. Added to that, bioinformatics and genomic databases have transformed biotechnology more from laboratory-based techniques to computer-based science, positioning new problems to intellectual property laws. Aside from the political consequences, the gene and gene fragments' patents have immense influence on the society and policy making. Such persons as legal practitioners, law students and researchers, scholars, those who are interested in interdisciplinary research and regulation, individuals interested in biotechnology and the regulation of the intellectual property rights study this topic very keenly. The assessment of social and policy repercussions of genetic patents is mainly based on accessible literature and evidence. Given the fact that science of biotechnology is technology of emerging nature, it will be difficult to come up with definite solutions; nevertheless, we will strive to provide an insight of law–biotechnology interface, identify emerging issues and give some possible solutions to the existing problems.

The idea of human gene and gene fragment patentability has got legal, social and policy implications which go on (beyond) the very accessible use of genetic research tools, genetic innovation, health policies, patients' rights, clinical practice and to the society as a whole. The commercially exploitable potential of genetic scientific research resulted to the rapid commercialization of basic science through favorable agreements and patents. The sale of basic genetic information is undermining the principle of free passage and the open study field of academia. The intensive commercialization of the genetics research at the upstream (earlier) has been attributed to the patenting of gene fragments like ESTs and SNPs which are utilized as research tools only. However, genetic patenting would restrict genetic innovation to the extent that researchers may have to face difficult conversations with patentees concerning the license terms before the use of such research materials. Patents on genetic tests nowadays - particularly in diagnostics — have also opened up a whole new area of controversy. Too broad patents and frequently described patent assertions lead to less creativity development. A US multinational health science company Myriad Genetics Corp, which holds patent rights to breast and ovarian cancer genes BRCA1 and BRCA2, entails multiple social and policy implications in patents tied to genetic testing.

The novel approaches in the field of molecular biology and genetics, resulted in the restructuring of basic genetic studies. The possibility of academical genetic research culminating in commercial gains has established close relationship between intellectuals and businesses. The government of other countries therefore, thinks that this is an ongoing trend, as they believe that their national economy will profit significantly if universities perform research. There has been a tremendous burden on publicly-organized institutes committing research findings for commercial use. The university patents acquisition has now even proved to be a sign of academic good progress. Consequently, patents cover a broad spectrum of findings by life sciences researchers. In the USA there was an issuance of more patents on DNA sequences to the researchers in universities compared to the industries.

The initiation of the connection between the university and the industry dates from a while ago and the passage of the famous Bayh-Dole Act in the USA in 1980. Act with this University owning IPRs of inventions from publicly funded studies. It makes the industries partner in the re-

search and get individualized advantages by a patent or other intellectual property right agreements.One of the fundamental stimuli to commercialization of newly developed technologies adopted by the Congress of USA was encouraging educational institutions and other organizations to patent discoveries made with other than private funds, and to license those technologies to private business. In other locations, like Canada and Europe, where the intellectual property law equivalent to Bayh–Dole act was absent, universities focused on improving the capitalization activities. A case in point is Canada which stressed on tripling thenumbers of commercial projects adopted by the universities by 2010 through the 2002 Framework on Federally Funded Research. The speedy way the venture capitalists are seeing success in their investments is causing a dissolution of a line between academic (non-commercial) and commercial research. Currently, private sector funds most early-stage research in biomedical sphere, it is being conducted in private institutions or by means of patents, trade secrets and agreements limiting usage of data and material.

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Сравнительный анализ политики патентования генов человека

Аннотация: Посвящается сравнительному анализу политики патентования генов человека. В статье анализируется включение генов, в том числе гена человека, в национальное патентное законодательство стран. Определяется и обосновывается использование методов диагностики для лечения человека, растений и животных с использованием патентных прав.

Ключевые слова: ИР; патент; ВТО; ДНК.

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