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Changing landscape in biotechnology patenting

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ABSTRACT

Trade regime of the world has brought into focus the ability to generate and secure IPR. The transformation has been rapid and recent decades have seen an increase in intellectual property protection worldwide. The Patent Cooperation Treaty (PCT) has, since it began in 1978, seen continuous growth with a record 156,100 application filed in 2007, representing a 4.7% growth over the previous year. Most academic patents applied for are in biotechnology or related fields. The paper identifies the effect of the changing landscape in biotechnology patents. Changes in specific areas like transgenic crops, nanotechnology, pharmaceuticals etc. are also discussed along with trends like the increase in patent applications by educational institutes across the globe. Certain problems pertaining to patenting of biotechnological innovations that have arisen in recent times are also discussed.

1. Introduction

Biotechnology can be defined as the collection of technologies that capitalize on the attributes of biological systems, processes and organisms along with their contributions to manufacturing industries and put molecules such as DNA and proteins to work for us. The foundations of modern biotechnology were laid in the first half of the twentieth century with a transition from the Age of Chemistry to the Age of Biotechnology that has and is going to witness an expansion of the global economy, increasing wealth while reducing humankind's dependence on environment.

The products of the innovative efforts need to be protected including the financial investments by strong intellectual property (IP) laws. Patents are the most important way in which researchers can protect the income that might come from ideas or technologies they have developed. The steps involved and the considerations needed for successful granting of a patent have been described by Latimer [1]; for instance, inventions must be novel and non obvious, adequately described, and industrially applicable. The patent rights being territorial in nature are enforceable only within the country, which grants the patent. The non-patentable conditions generally differ from country to country with different subject matter considered fit for patenting.

Effective intellectual property protection and enforcement contribute to the growth, development and success of human invention involving biotechnology [2]. Countries across the globe are now vying for competitive edge for leadership in the global market through technological growth and development. Various companies in recent times have started registering intellectual property in their name. Patents are now seen as a potent indicator of the status and competitiveness in the modern world.

2. Changes observed

It appears that the next wave of technological innovation in this century will arise from the life sciences and biotechnology. Today, the spectrum of accumulated knowledge in biology is immense and far more extensive than any individual can assimilate. The 20th century witnessed remarkable achievements in science and technology, particularly in the area of molecular genetics. The implications of the DNA discovery have been enormous, and we are still only at the beginning of the revolution that began 55 years ago. The discovery opened the gateway to the modern era of biology and medicine. The spectacular discovery has altered the way of thinking about biological problems, ushering in a whole new era of science. The finding was so fundamental to uncovering the inner sanctums of life that much of biological research today is still building on it. Nobel Prizes in Medicine and Chemistry have often gone to molecular geneticists and biochemists since 1955. This is evident from the fact that roughly 10 Nobel prizes in Medicine or Physiology were given only in the area of Molecular Genetics (1955–2000) making it single largest discipline (25%) in comparison to other areas (average 3%). (http://nobelprize.org/nobel_prizes/medicine/articles/lindsten-ringertz-rev/index.html).

As many as eight prizes have been awarded in Chemistry for biochemical discoveries in the second half of the century illustrating

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the explosive growth of biochemistry in recent decades (eight prizes in 1970–1997) (http://nobelprize.org/nobel_prizes/chemistry/articles/malmstrom/index.html).

However, it is expected that 21st century will flourish with the aid of the expansion of computer technology and the study of biological systems may become more dominant and move from individual macromolecules to large interactive systems [3].

With the sequencing of the human genome and advances made in plant and animal genetics and other aspects of the life sciences, these technological breakthroughs provide the building blocks for what are likely to be major industries with profound implications for agriculture and human health. Not only will humankind benefit from new innovative technologies but will also have the opportunity to contribute to the advancement of scientific knowledge and the development of the global biotechnology industry.

Recent decades have seen an increase in intellectual property protection worldwide [1]. The ruling that a live, human-made, genetically engineered bacterium (that was modified to break down components of crude oil) could be patented initiated an era of progressive private investment in biotechnology and of rapid expansion in the patenting of new biotechnological innovations and products (US Patent No. 4259444). Many biotechnology companies and universities have since applied for and been granted patents on a wide range of biotechnology processes and products, involving genes, viruses, bacteria and even higher living organisms.

With the advent of this new trend of patenting, there has been an increase in apprehensions about the methods of implementation of these new technologies and distribution of the same. Such concerns are normally associated with new and rapidly changing landscape of intellectual property rights (IPRs). Biotechnology patents are no different. With the growing industrial importance of biotechnology and the massive investments and efforts being made in R&D all over the world, the question of securing adequate protection for the new and revolutionary technologies in this field has assumed considerable importance [4,5].

Patent cooperation treaty or PCT has made it easier to file patent applications in many countries at the same time and is more streamlined mechanisms for applying patent protection. There is already a Community trademark; a Community design will be available soon, as will in due time the Community patent [6]. A decade ago applications for IP were paper based and there was little or no communication between patent offices in different countries. Now with the advent of internet and the expanding usage in different nations particularly the developing ones, has enabled successful integration of patenting databases around the world and sharing of information is both efficient and convenient. Still searching and analyzing biotech information in patent and scientific literature seems to be a daunting task.

The PCT process is perhaps the nearest thing there is to a 'global patent' system. The PCT has, since it began in 1970, seen continuous growth with a record 156,100 application filed in 2007, representing a 4.7% growth over the previous year [7]. The most remarkable growth rates came from countries in North-east Asia for the third year running and represented over a quarter (25.8%) of all international applications under the PCT. In 2007, the list was topped by applications from the USA, Japan, Germany, Republic of Korea and France. The number of international patent applications continues to rise with impressive growth from North-east Asian countries. With more than 52,000 PCT applications, inventors and industry from the USA represented 33.5% (a 2.6% increase over 2006) of all applications in 2007 [7]. Increasingly developing countries are capitalizing on the tools of the intellectual property system for enhancing their wealth [5]. Innovation has been traditionally dominated by Europe and North America, however, new centers of innovation are emerging fast in North-east Asia and this is transforming the future global economic growth along with the geographical distribution of intellectual property.

World Intellectual Property Organization (WIPO) continued to receive International patent applications from developing countries in 2007. The largest number of applications received came from the Republic of Korea (7061) and China (5456) followed by India (686), South Africa (390), Brazil (384), Mexico (173) Malaysia (103), Egypt (41), Saudi Arabia (35), and Colombia (31). Developing countries make up 78% of the membership of the PCT, representing 108 of the 138 countries that have signed up to the treaty to date. During 2007, 2 new contracting states became bound by the PCT, namely: Angola (from 27 December 2007) and the Dominican Republic (from 28 May 2007) bringing the number of states which had acceded to the PCT by 31 December 2007, to 138. Among the PCT applications published in 2007, pharmaceuticals sectors accounted for 9.3% of all applications. This further shows the dominance of biotechnology and related fields in today's market and the potential for rapid growth.

2.1. Changes in specific areas

One of the issues relating to patenting of genetic inventions revolves around the question whether a DNA sequence is a discovery or an invention. This is a highly controversial topic, with vehement opposition from either party. In Europe, the recently issued Directive on Biotechnology clearly distinguishes between a discovery and an invention [8]. The Directive makes it clear that genes or other elements isolated from their natural environment and which have a proven technological effect are patentable by law [9].

In the last two decades or so, there has been a great deal of effort within the pharmaceutical industry to identify potential lead compounds by testing combinatorial chemistry libraries against biological targets using fast throughput screening techniques [10]. Increased activism and political confidence in the developing world, allied to the reawakened interest of Western medicine in plant and animal derived compounds, will likely make for a turbulent interface between the classical protection of intellectual property rights and the assertion of traditional rights [11]. It might be said, therefore, that there has been an observed trend over the past two decades with the mindset of researchers and inventors swaying away from the idea of publicly shared ownership of biological/genetic resources towards personal ownership and licensing of IPR.

The effects of changing patenting priorities in the emerging global leather trade have been reported by Chakrabarti et al. [2]. Changing direction of global research in leather research as indicated by generation of patents has been mapped as well. The trends that the authors report indicates that product oriented research and bio-product alternatives to chemical inputs in leather processing are gaining higher significance as well as a sustained interest. Exclusive monopoly over patents on nano-scale materials, devices and processes is also a much sought after concept among biotechnology based industries today. The US National Science Foundation (NSF) has predicted that the broad scope of nano-scale technologies posses the ability to revolutionize manufacturing across all industry sectors-capturing a $1 trillion market within six or seven years. At first glance it might seem that nanotechnology is still in its infancy, but it should be kept in mind that the list of patents on nano-scale materials, tools and processes is expanding at a phenomenal pace.

Plant breeding practiced over the centuries has produced crop cultivars that sustain humankind today. Modification of crops is not new, and biotechnology, in a very broad sense, has been used for over a century to accelerate the development of new crops so as to meet the demands of a fast growing global community. The development of novel biotechnological tools of direct gene transfer, in the last decade and a half, has added new dimensions to plant improvement programmes. The development of 'First Generation of genetically engineered (GE) Crops' (in-put traits such as insect and pest resistance), 'Second Generation of GE Crops' (out-put traits like enhancing the nutritional level) and 'Third Generation of GE Crops' (plants as factories-renewable) are some of the accomplishments of transgenic technology. Transgenics have implications to facing the demographic, technological, economic, equity, ethical and ecological challenges [12]. However, like any new technology, transgenics have aroused public concerns. The fear of the unknown has led to use of a precautionary regulation of genetically modified crops (GMC), such that research and development are hindered. As a result of this approach, licensing and marketing are delayed or halted altogether. The public concerns are often genuine because no technology is completely risk-free and therefore we must weigh potential benefits against any possible adverse effects of the new technology on the environment, and human and animal health [12]. Modern biotechnology can help, provided the research agenda is based on considerations of public good, rather than only commercial profit, in meeting these challenges in a socially meaningful manner.

The IPR surrounding the creation and ultimate deployment of transgenics is a key issue and cannot be isolated from the technological aspects of this endeavour. Issues of ownership, access and risk are fundamentally affected by the patenting of seeds by the private sector. Livelihood strategies such as seed-sharing (from seed banks) and the re-use of seeds over a number of seasons are threatened when seed banks are controlled by commercial companies and smaller seed companies are bought out, reducing the availability of unpatented and non-hybrid seeds. Rural community's self-sufficiency and security are potentially threatened by these new patterns of control [13]. Intellectual property regulations enable the genetic appropriation of unpatented seeds from around the world, to modify a single gene of these seeds and then patent and acquire exclusive rights over them. Ethical issues are thus gaining greater importance, as the extraordinary opportunities opened up by transgenics expand.

Ethical issues assume greater importance in medical biotechnology in areas such as stem cell and human cloning. The use of gene patents in medicine for diagnostic purposes has raised public issues and concerns around the world [14–16]. The main arguments against patenting of genes are: (i) genes being natural entities can not be owned by any body; (ii) genes being discoveries have no element of novelty or inventiveness and thus do not qualify as invention; (iii) the processes for isolation and cloning of genes are well known.

From ethical perspective biotechnology is challenging and it is becoming equally clear that unless the technological push is matched by an ethical pull, the products of our intellect may become a curse rather than a blessing. Already the Human Genome Diversity Project has encountered problems from ethnic minorities concerned with possible exploitation of their genetic information. Patent protection and expanding IPR regime, together with the control of technologies by a few large multinational companies (MNC) has led to fear that rich-poor divide in technologies empowerment will grow further.

Thus, ethical challenge relates to an expanding IPR environment in biotechnology research. Patents will make vital discoveries exclusive and will result in social exclusion with reference to sharing the benefits of invention important in food and health security [12]. This will further increase the rich-poor divide. The ethical aspects also related to farmer's right prior informed consent and benefits sharing with reference to biodiversity. If these issues are not resolved, accusations and biopiracy will grow. We need to foster mutually beneficial partnerships and eliminate biopiracy as far as inventions relating to biotechnology are concerned [12].

Trade Related Aspects of Intellectual Property (TRIPs) does permit certain plants and animals, other than microorganisms, to be excluded from patenting, as well as essentially biological processes. TRIPS also allows inventions to be excluded from patenting if it is necessary to protect human, animal or plant life, the environment or morality. Diamond v. Chakrabarty and Harvard Oncomouse are two important cases in the field of biotechnology patents that have been raised in relation to patenting live organisms. At the national/regional level, various approaches have been taken in different countries on patenting of higher life forms, and to take account of moral issues (WIPO Course Module 2008) [17]. For example, the European Patent Convention (EPC) provides that patents for animal and plant varieties are specifically excluded (EPC Article 53(b)). Also, the European Patent Office will not grant patents containing claims to the treatment of a human being via biological or other means. In Australia, for example, the Patent Act 1990 (s18(2)) allows patenting of inventions using microorganisms, plants and animals but not human beings and the biological processes for their generation. The US patent law (Title 35 U.S.C. 101) provides for the issuance of a patent to a person who invents or discovers "any" new and useful "manufacture" or "composition of matter." In 1988, a patent was granted to an invention of the oncomouse (US Patent No. 4736866). It was the first patent for a genetically modified animal for medical research. The Supreme Court of Canada, on the other hand, has ruled that higher life form, such as a transgenic mice, is not patentable because it is not a "manufacture" or "composition of matter" within the meaning of invention. In Japan, the law excludes from patentable subject matter mere discoveries of microorganisms existing in nature and inventions of microorganisms *per se* which are incapable of industrial application because their utility is either not described in the patent application or cannot be inferred. In India, under Section 3(j) of the Patent Act, plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals, are not considered as inventions and are therefore not patentable.

2.2. Changes across Europe

Although patents involving human embryonic stem cells have been granted in USA and some other countries, the situation in Europe has been complicated by ethical exclusion clauses in the European Patent Convention and the European Biotechnology Directive [18,19]. Such delays in processing these patents by patent offices across Europe have hindered the progress and marketing of research in this area. Although ethical and other concerns in this area are not entirely justified, it does not exempt us from or hide the delay in coming up with efficient treatments for diseases like cancer which is responsible for high mortality rates in countries at all levels of development. It has been concluded by some [18] that ethical exclusion from grant of patents may not be appropriate. Recently, some European countries such as Denmark, Germany, Austria and Norway reformed their IP laws to grant IPRs to universities [20], others are considering similar reforms. Debates on the patenting and licensing of genetically engineered flora are not devoid of such issues either. It has been pointed out by Perdue [21] that the landscape for patenting transgenic plants in Europe is also changing rapidly [9].

Another factor hindering the biotechnology industry in Europe is the lack of certainty concerning intellectual property protection for biotechnological inventions. The inventors in both academic and industrial arenas are circumspect about the chances of their patents being granted, even though the research satisfies the criteria of patentability. The established principles of novelty, inventive step and industrial applications are more often than not, adequate to decide the patentability of the vast majority of biotech inventions based on European Patent Law [9].

European Commission (EC) Directive gives a list of biological inventions which should be regarded as non-patentable on grounds of public order and morality. It includes:

- Processes of cloning human beings.
- Processes for modifying the germ line genetic identity of human beings.
- Use of human embryo for industrial or commercial purposes.
- Processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to man or animal, and also animals resulting from such processes.

Fears surrounding human gene patents have, for the most part, yet to manifest themselves in patent litigation [14,15]. European Union regulations that are overly strict and restrictive in nature have also been blamed for stifling the development of biotechnology in Europe and elsewhere. For example, the new EU regulation halted the release of genetically modified (GM) food and feed in developing countries. The consumer and policy resistance towards GM foods by EU are barriers to placing GM seeds in hands of farmers in developing countries [22]. The Third World countries have thus opted for "precautionary concerns" about biological safety. The main reason seems to be the fear that consumers in high-income countries such as in Europe will shun imports from any country that plants GM varieties.

2.3. Changes across India

An upward trend during the years 1977–1991, i.e. from 14.6% during 1977–1981 to 16.7% in 1982–1986 and 27.4% in 1987–1991 has been reported as far as patenting and the contribution of biotechnology patents in India are concerned [4,5]. Fig. 1 gives a projection of biotechnology patents filed against the total number of patents filed for the last one decade (Source: Intellectual Property Office, India Annual Reports) [23]. There has been a sharp rise in the last 5 years. This increase in biotechnology patents can possibly be attributed to amendments in the Patents Act (1970) in 2002 and then WTO (TRIPS Agreement) obligations for product patent from 2005 as per which, product patents can be granted for pharmaceuticals, chemicals, agrochemicals and food. It is now possible to grant patents in biotechnology too, particularly for vaccines, antibodies and diagnostic kits. However microorganisms occurring in nature are still excluded from patenting under the law [24].

3. Academic patents

Academic institutions have become major players in patent arena and there has been a rise in number of academic patents (Fig. 2). For instance in US the number and percent of total patents assigned to US academic institutions generally have increased (just under 2.0%) since 1985 when only 589 utility patents (0.82%) of the total, were assigned to US academic institutions (http://www.uspto.gov/go/taf/univ/univ_toc.htm).

Biotechnology is an emerging sector in which academia has been one of the main actors [25,26]. In last one decade, some 50% of all patents issued by research-intensive US universities were developed in life sciences [26]. In Belgium, academic patents are even more tilting towards biological and medical inventions: on an average 75% of the patents applied by Belgian universities at the European Patent Office (EPO) between 1985 and 1999 were in biotechnology [27]. The number of Italian university patents has also risen substantially. Patenting activities almost tripled in universities with an internal IPR regulation [28].

Significant changes have been observed in the patenting behaviour of European universities over the past one and a half decades. These changes have been driven by the biotech revolution and by recent Bayh-Dole Act-like regulations that is aimed at fostering the patenting of academic inventions. As a result of these changes, a higher propensity to patent academic inventions has been observed [9,29–31]. At the same time, scholars and policy-makers have underlined the crucial role played by industry-university partnerships in the knowledge society [32–36].

The rampant growth of patenting and subsequent licensing of publicly funded research by American academic institutions towards the end of the last century has occupied centre stage in some of the most infamous and aggressively pursued debates in science and technology today. The movement of academicians into commercialization of their inventions has been touted by some as a new model of academic research [37], one which facilitates economic and social returns from universities. Simultaneously, this new trend in the biotechnology sector has been criticized by many as it leads to privatization of academic research. This, as pointed out by many, is against the accepted ethics and principles of science. For instance any advances in agriculture biotechnology are

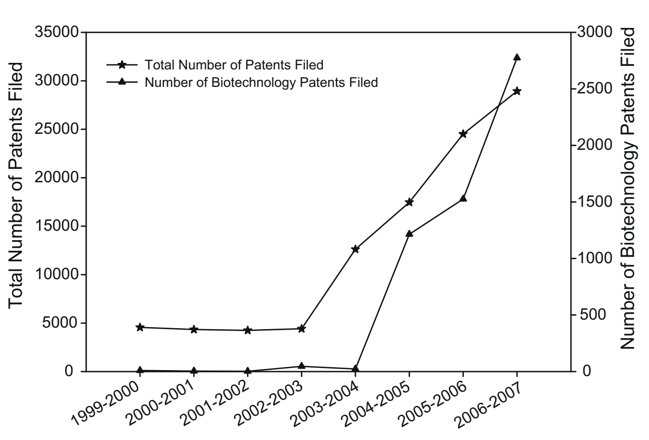

Fig. 1. Number of biotechnology patents filed vs. total number of patents filed per annum at Indian Patent Office (Source: IPO Annual Reports).

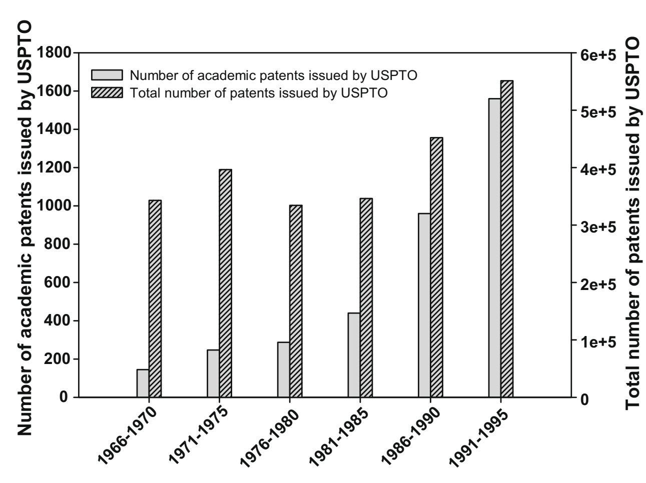

Fig. 2. Number of academic patents issued vs. total number of patents issued by USPTO. [Source: Y values derived from Sampat [37] and Y1 values – http://www.uspto.gov/go/taf/us_stat.pdf] Ref: Rangan 313.

useless if farmers cannot have access to it. The small and marginal farmers in developing countries could be deprived of benefits of technological breakthrough simply because they do not have the resources to pay for the new technologies. The greater trend towards privatization and a stronger regime of intellectual property protection will thus threatens to put enormous burden on the farming communities leading to a further expansion of the rich-poor divide in terms of technological empowerment. This "privatization" of public sector research has blurred the line in terms of those international bodies that are accessing research materials. As a result, it can be argued that it is no different in essence to negotiate a license agreement with a major university than with a multinational company.

Henderson et al. [38] show that the patent surge is associated with an overall increase in university attention to commercial applications of technology, but that there is no increase in the number of very important patents, probably because institutions with little experience and expertise have entered the patents playing arena.

4. Discussion

The relatively recent trend toward the globalization of IP is in sharp contrast to two decades ago when IP was used predominantly by a few individuals working in tandem with their patent departments. The growing need for more sophisticated and more highly integrated IP strategies is better understood in the context of the globalization of IP [6]. Presently, IP is an essential factor for any organization, both industrial as well as academic. Online databases of many important countries, including India, US, Italy, Canada etc., have been documented recently [39].

Researchers who come up with biological inventions are often caught unaware by the vast plethora of problems that they encounter while trying to acquire their IPR over the inventions as compared to their counterparts in electronics and mechanics. These difficulties have been attributed to the more complex and unpredictable nature of biotechnological innovations [1,40]. There is also increased pressure being applied for reductions in translation costs and patent office fees, for more data quality, and for process simplification to ease this torrid process of acquisition of IP by inventors.

An increasing number of international research and governmental institutions are challenging several gene patents, arguing that the patent holders' absolute control of diagnostic methods is not in the public's best interests [19]. A commercial approach to health care also goes against the common perception of public health [41]. European countries might lead the debate about gene patents while other countries are slowly but surely getting involved in the argument. The ultimate goal is to put the health tools within reach of the entire healthcare system while enabling researchers to perform research to improve and perfect the available testing techniques.

After a decade of confusion and controversy over biotech patents, governments are now facing a newer, bigger technology wave. By 1 July 2013 even 'least developed' countries will be obligated by the World Trade Organization's Trade-Related Aspects of Intellectual Property to accommodate nano-technological inventions. Despite predictions that nanotech will pave ways for alternative methods of improving health, sustainable energy and environmental security, researchers in developing countries are likely to find that participation highly restricted [42]. The unique potential of genetic engineering techniques for creating tailored designed crop plants such as virus resistant, drought tolerant and nutrient-enhanced crops cannot be ignored, while acknowledging that there are environment and health issues that need to be addressed [43]. Any technological innovation in society will have concerns and perhaps cost associated with it. To date, empirical observations indicate that there have been no documented problems associated with GMCs [44]. However, it is important to listen to the critics of biotechnology and learn from them and evaluate their concerns. Therefore, it has been suggested that regulation of genetically modified/engineered plants, crops and animals should move towards a product risk-benefit analysis, in other words, a case-by-case evaluation of any new organism, regardless of as to how it was developed. Positively influencing the public opinion will remain to be the biggest challenge and responsibility.

A number of scenarios for future trends and new developments for patent information have been explored recently [45]. It is expected that as a consequence of large public and private investments in new biotechnologies, there will be an increase in the filing numbers of European and PCT patent applications, especially those related to nanotechnology at the EPO in the coming years [46].

The recent scientific advancements in the field of biotechnology have led to the development of Technology Protection System (TPS) commonly dubbed as "terminator technology". The MNC who have spent millions of dollars in developing technology are keen to exploit the opportunities and are trying to introduce such protected technologies in developing countries which represents obvious market for them. Advocates of terminator technology claim that the technique would ensure a good crop protection with more safety aspects. From the point of view of such a company the royalty it gets from the sale of seeds is its primary source of income. But can the fact be ignored that "human safety at the cost of food security be our motto".

5. Conclusion

To summarize the above points, the foremost observation is that the IP scenario has undergone significant changes over the past few decades, especially with regard to biotechnological innovations. What was an upcoming field a couple of decades ago, is now a force to reckon with. As has been discussed earlier, biotechnological patents now form a major chunk of all patents, in particular the academic ones filed by educational institutes across the globe. Among biotechnology patents, the fastest growing are applications for novel pharmaceuticals [10]. While other fields like nanotechnology and genetically modified organisms (GMOs) are close behind.

This rise in intellectual property has not been free of controversies and this as with any new technology; it is currently going through a phase of intense development and a slow but steady process of convincing people about its importance and sustainability. Possible new configurations can be proposed, but it is impossible to predict which changes will occur and when. To obtain market exclusivity, biotech companies need to be aware of how science and patent law interact. Scientific issues affecting patentability, competent legal counsel, and inconsistencies in the way courts apply and interpret biotechnology patent law can all affect a company's ability to obtain, and retain, market exclusivity. Therefore, judicial developments will continue to define the scope of patent protection and guide the future [47]. This monopoly over existing innovations and the associated restrictions are already creating obstacles for researchers and innovators alike who would like to work on similar lines.

Biotech inventions are challenging from ethical perspectives too. There is substantial opinion against patenting of genes: it is feared that once genes become private property, full benefits of genome decoding will not be available; the counterpoint advanced by drug developing companies is that without patent rights, it would not be possible to fund research into new drug development. The control over human DNA, which is already possible to a limited degree in applications of genetic screening and gene therapy, raises the issue of genetic selection and eugenics [14,15]. The Harvard Oncomouse and Chakrabarty cases show how assessments on ethical issues in relation to patents have been made. New technologies, such as somatic cell gene therapy, have entered clinical trials in many countries, for a wide range of diseases and purposes. People in Japan, New Zealand and USA have been shown to support the use of human gene therapy, though they may still have some concerns about it. We need to elevate the importance of individual autonomy, especially in reproduction, while at the same time limiting the use of new technologies by individuals. While we should not be afraid for society to change, we should be very cautious about possible and adverse changes in social attitude because social pressures are very difficult to control.

Strengthening of IP protection will therefore call for a strong synergy between public and private entities in the field of biotechnology. However, strong IPR regime for biological inventions has weakened one of the historical justifications for public support of agricultural research i.e. the inability of private entities to sufficiently profit from research. But there seems to be greater knowledge spill-over by facilitating broad dissemination of research findings though. Public research organizations should be pursuing intellectual property protection as vigorously as private firms. A strong public sector role in conducting a well funded research and pursuing IP protection will not only ensure a larger pool of R&D for the nation but also broad dissemination of new discoveries to other scientists and innovators who can advance and apply them [48]. The public sector has critical assets in the form of germplasm and associated biological knowledge important in new science of genomics. However to fully exploit these assets, public sector must develop a capacity in IP management, strengthen biosafety protocols and upgrade business skills.

Biomedical industry is where the issue most frequently arises, the remedy must address all areas of research no matter where carried out or how funded. American Intellectual Property Law Association (AIPLA) endorses the National Academy of Sciences US (NAS) Report's recommendation on reaping the benefits of genomic and proteomic research, that a legislative solution be expeditiously sought (www.aipla.org). AIPLA further aims at fostering more innovation and greater dissemination of technical knowledge that in turn should instruct the policy choices made in crafting patent laws. Finally, the codification of an experimental use doctrine is especially important today, given the broad reach of the patent law world wide.

With respect to patent granting on a global scale, following ideas have been put forth by Akers [6], but probably have a long timeframe before it is being fully realized.

- Fully electronic patent system
- Globalisation of patent office web sites
- Single filing and granting system for global patents
- Common language in patent documents

While these ideas are not specific for biotechnological patents, in view of the recent trends in the biotechnological sector, implementation of such practices should be given utmost importance. The rate at which this sector is growing, piling up of patent applications with little hope of acquisition of rights will do more harm than good. Rapid commercialization of innovations of global importance, golden rice for example, can help feed millions across the planet who suffer each day on account of malnutrition. Same holds true for other genetically modified organisms. Pending health patents that are engulfed in controversy over ethical concerns should also be evaluated on a case to case basis to help save the people who fall prey to the associated disorders and have a chance of survival and an improved life upon successful use of the biotechnological innovation.

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