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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