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COMPARISON OF THE U.S. AND THE E.U. BIOTECHNOLOGY APPROACHES AND POLICIES FOR PREDICTION OF PROSPECTS FOR TURKEY

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ABSTRACT

The starting point of this thesis is to predict what kind of a political strategy Turkey should determine in the field of biotechnology and what the solution can be to resolve the policy defectiveness. Therefore, the U.S and the E.U. taken as two different examples and comparison of indicators that determine the success criteria has been done. It is the same indicators used for Turkey's current condition analysis in order to determine the appropriate strategy**.**

Although the results that deduced from the chosen indicators and from the compared data related with these indicators for comparison of the U.S. and the E.U policies are open to discussion both from legislative, economic and social aspects, it can be said that the U.S.A's strategy is focused on final aims and provides the desired results from the side of the U.S. From the E.U's side because there is no clear attitude determined about applications in the field of biotechnology a clear policy or strategy can not be mentioned. This situation derived from two reasons. The first one is the U.S. get to first base in biotech and therefore gained advantages over its competitors. The second one is the E.U's protectionist approach resulting from its trade and competition concerns.

The situation is somewhat different than these two models for Turkey because bureaucratic restrictions, economic and technological dependence of Turkey are the two main difficulties to determine the appropriate strategy. In principle resolving these two difficulties should be the initial target of biotech policies in the first place. What is left to do is to activate the existing potential of Turkey and taking legislative, economic and social measurements against external factors.

ÖZET

Bu tezin çıkış noktası biyoteknoloji alanında Türkiye'nin nasıl bir politika stratejisi belirlemesi gerektiğine dair öngörüde bulunmak ve politika eksikliklerini gidermek için çözümlerin neler olabileceğine dair cevaplar bulmaktı. Bunun için A.B.D ve A.B iki farklı örnek olarak ele alınıp başarı kriterlerini belirleyen indikatörlerin karşılaştırması yapılmaya çalışılmış ve aynı indikatörler baz alınarak Türkiye için durum değerlendirmesi yapılarak uygun stratejinin belirlenmesine çalışılmıştır.

A.B.D ve A.B'nin politikalarının karşılaştırması için seçilen indikatörler ve bunlara dair verilerin karşılaştırmasından çıkarılan sonuçlar gerek hukuksal, gerek ekonomik, gerekse sosyal açılardan tartışmalara açık olsada, A.B.D'nin bu konuda izlediği stratejinin sonuç odaklı olduğu ve istenen sonucuda A.B.D açışından sağladığı söylenebilir. A.B'de ise biyoteknoloji alanındaki uygulamalar konusunda net bir tavır belirlenemediği için net bir politika stratejisinden de bahsedilememektedir. Bu durum iki nedenden kaynaklanmaktadır; birincisi A.B.D'nin biyotek konusundan daha erken yol alması ve dolayısıyla rakiplerine karşı avantaj elde etmesi. İkincisi ise A.B'nin ticari ve rekabet kaygılarından doğan korumacı yaklaşımıdır.

Türkiye için ise durum bu iki modelden biraz daha farklıdır çünkü Türkiye'de ki bürokratik engeller, ekonomik ve teknolojik bağımlılık sorunu, uygun stratejiyi belirlemede en büyük iki engeli teşkil etmektedir. Esas itibariyle bu iki engelin ilk etapta kaldırılması biyotek politikasının ilk hedefi olmalı ve geriye varolan potansiyeli aktif hale getirmek ve dış etkenlere karşı hukuksal, ekonomik ve sosyal önlemlerin alınması kalmalıdır.

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LIST OF ABBREVIATIONS

ATTC	The American Type Culture Collection
BRCs	Biological Resource Centres
CCs	Culture Collections
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
DBFs	Dedicated Biotechnology Firms
DG	Directorate-General (of the Commission of the European Communities or shortly European Commission)
DNA	Deoxyribonucleic Acid
DSB	Dispute Settlement Body
DSMZ	German Collection of Microorganisms and Cell Cultures
E.U.	European Union
EC	European Community
EPC	European Patent Convention
GATT	General Agreement on Tariffs and Trade
ICABR	International Consortium on Agricultural Biotechnology Research
IISD	International Institute for Sustainable Development
IPPC	International Plant Protection Convention
IPRs	Intellectual Property Rights
NIG	National Institute of Genetics
NTBs	Non-Tariff Barriers to Trade
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development
SPS	Sanitary And Phytosanitary
TBT	Technical Barriers to Trade

TK	Traditional Knowledge
U.S.A/U.S.	United States of America
UNCED	United Nations Conference on Environment and Development
UNEP	United Nations Environment Programme
USOTA	United States Office of Technical Assistant
WCMC	World Conservation Monitoring Centre
WDCM	World Data Centre for Microorganisms
WFCC	World Federation of Culture Collections
WHC	World Heritage Convention
WTO	World Trade Organisation

I. INTRODUCTION

The purpose of this study is to compare biotechnology policies of the E.U. and the U.S from political, economical and legislative points of view to determine and suggest the best policy approaches for Turkey.

Biotechnology is defined as "the use of accumulated knowledge in life sciences through mathematics and engineering methods" and based on that definition biotechnology peformance of Turkey is well below its capacity. One obvious method of finding out the reasons of that low performance problem is through observation and comparison of different but comparable applied real models and applied real approaches to biotechnology and their successes and failures. In that regard a systematic comparison between the E.U. and the U.S. biotech policies would be useful for Turkish policy makers because Turkey has somewhat integrated to both of them in several ways, e.g. through NATO to the U.S. and through full membership application to the E.U. There are also differences between the biotechnology policies of the U.S. and the E.U. that should be understood throughly for prediction of prospects and policy making for Turkey which are already affecting Turkey directly or indirectly. The comparison of the U.S. and E.U. biotech policies would be a conclusive choice because they are related and comparable to each other due to cultural and political paralles in historical terms, though with obvious policy and approach differences on biotechnology and of course performance differences based on that policies and approaches.

There are several indicators chosen in this study for better understanding of the differences of the U.S and the E.U. approaches and resulting peformance profiles due to those differences. One of the major indicators used in this study is their regulations such as intellectual property applications (e.g. patenting new inventions, regulations for production and trade of GMOs), binding international treaties, or if they are a party of an

international treaty at all. Microbial culture collections and cultures, number of patents of the U.S. and the E.U. are also compared in this study as well to investigate determining parameters. Market shares of genetically modified organisms, legislative procedures that sets the trade of them, venture capital investments and dedicated biotechnology firms are also compared in detail to reach conclusions and suggest policies and solutions for Turkey.

II. REVIEW OF THE LITERATURE

Overview

Biotechnology is a kind of subject that has a wide literature because of its multidiciplinary structure. During the researches, wide range of related books, reports and articles screened to find what exactly is useful in the scope of this study. After all this extensive research, indicators chosen for policy comparison of the U.S. and the E.U. but just these indicators themeselves do not mean anything for a person who is unfamiliar to biotechnology. Therefore, frame of the subject tried to be expressed in the literature review section by previous and recent studies and other references that contributes for a clear understanding of this study's scope.

Review of the literature section composed of four main parts. Yet there is no unique definition for biotechnology and this may cause confusion in minds. Because of this reason the first part highlights different definitions of biotechnology.

Biological resources are the raw materials of biotechnology, every industry using biological resources affected in one way or another by biotechnology, so this makes conservation of biological diversity one of the concerning issues of biotechnology policies. Value of biological resources, biological resource centres and key actors of conservation examined in details by addressing the issues in concern of biotechnology policies.

Intellectual property rights is another subject of biotechnology policy related topics. It shares the top of the list of the most controversial cases of biotechnolgy with genetically modified organisms. Benefit sharing through appropriate technology transfer and access to genetic resources, patentable subject matter and plant variety protection are the main

arguable points of intellectual property issues in the context of the Convention on Biological Diversity and the Trade-Related Aspects of Intellectual Property Right Agreement. The relationship between these two agreements is evidence of the interaction between intellectual property right protection and biotechnology policy.

Genetically modified organisms are another topic which finds wide interest because of the different approaches and so, different applications in regulations and trade of genetically modified products in worldwide. Non-market effects of genetically modified organisms, biosafety and legislative measures in international and national level are cited as the most interested areas of policy makers, industry, public and academic area.

2.1. Different Definitions of Biotechnology

2.1.1. Conceptual Definitions of Biotechnology

The term biotechnology, or biotech, maybe do not sound as a foreign term, nor a very complex technical word. In fact the definition of this word is not a simple work. There is no consensus on what biotech is. Notwithstanding it is hard to specify what really biotech is, generally there is a tradition that divides biotech into two phase as traditional and modern biotech.

Rochini Acharya states that the difference between the traditional and modern biotech is the technique used (Acharya, 1999). Likewise Acharya, Eric Grace mentioned that the techniques make modern biotech new, rather than the principle of using organisms (Grace, 1997).

U.S. Office of Technical Assitance (USOTA) defines biotech as, "the industrial use of recombinant DNA (Deoxyribonucleic Acid)[1] cell fusion and novel bioprocessing techniques". If a broader definition is chosen that includes also the older technologies as biotechnology, again USOTA defines it as "any technique that uses living organisms (or part of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses".

For a clear understanding it will be useful to define the word "technique" in the context of biotechnology. Acharya described the differences between the older techniques of fermentation and the modern techniques used today as an evolution over three distinct phases of technological change. First generation includes older and more common techniques that are used for everyday activities such as bread and cheese making and these are based on the use of bacteria in fermentation. Second generation as the broadest of the three technological categories includes systematisation of the scientific process of discovery and application. The systematic use of fermentation technology to produce penicillin and antibiotics can be an example. The third generation is to understand, alter or direct the function of a wide set of organic cells, including plant, animal and human (Acharya, 1999)[2].

Indeed these diffirences should not be taken as seperate biotechnology definitions or categorizations because biotechnology is an umbrella term that covers various techniques for using the properties of living things to make products or provide services. Today all biotechnological phases are in use by the industry and it will be wrong to take the biotechnology as only genetic engineering.

Biotechnology is a multidisciplinary field and its scope is wide. This makes hard to make a single definition. In Table 2.1. some definitions takes place but this list is not sufficient to see the whole picture.

[1] The molecule that encodes genetic information in the cells. It is constructed of a double helix held together by weak bonds between base pairs of four nucleotides (adenine, guanine, cytosine, and thymine) that are repeated ad infinitum in various sequences. These sequences combine together into genes that allow for the production of proteins.

[2] See Annex 1 for a brief information about historical development of biotech.

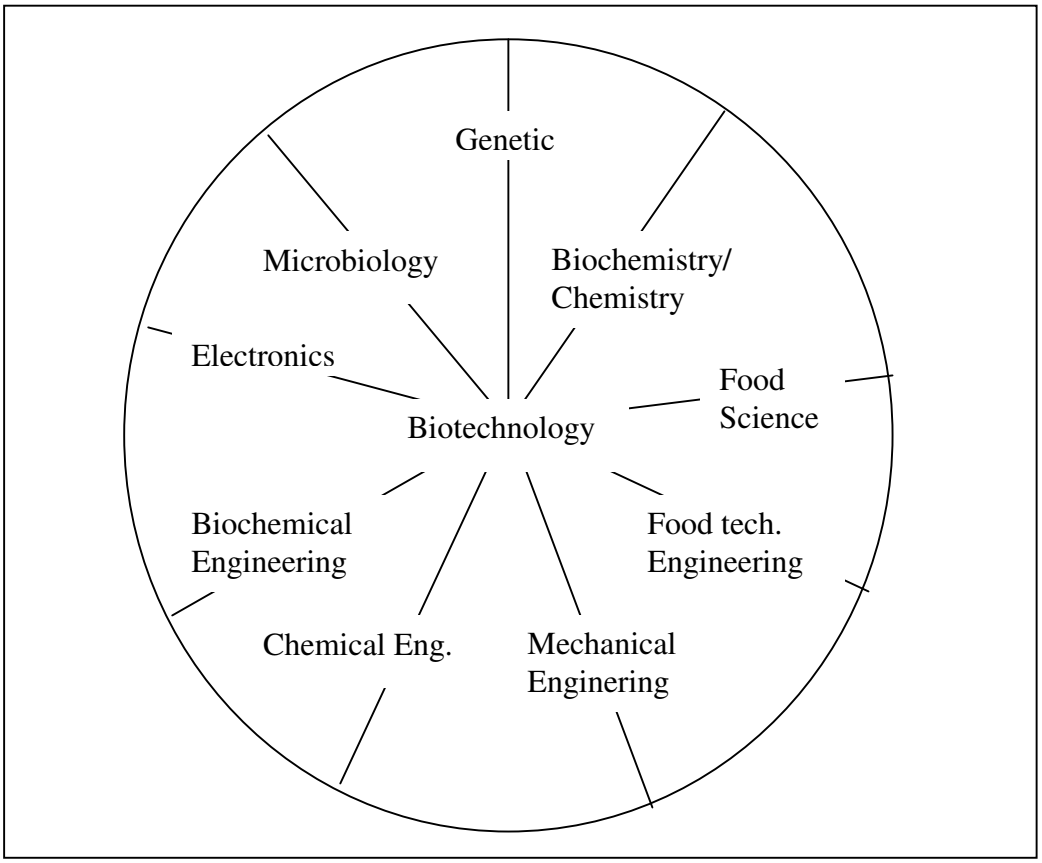
Table 2.1. Some Selected Definitions of Biotechnology

1. The application of biological organisms, systems or processes to manufacturing and service industries
2. The integrated use of biochemistry, microbiology and engineering sciences in order to achieve technological (industrial) application capabilities of micro-organisms, cultured tissue cells and part thereof
3. A technology using biological phenomena for copying and manifacturing various kinds of useful substances
4. The application of scientific and engineering priciples to processing of materials by biological agents to provide goods and services
5. The science of the production processes based on the action of microorganisms and their active components and of production processes involving the use of cells and tissues from higher organisms. Medival technology, agriculture and traditional crop breeding are not generally regarded as biotechnology
6. Biotechnology is really no more than a name given to a set of techniques and processes
7. Biotechnology is the use of living organisms and their components in agriculture, food and other industrial processes
8. Biotechnology – the deciphering and use of biological knowledge

Source: Smith, John E. (1997). *Biotechnology*. Third Edition, U.K: Cambridge University Pres

Interdisciplines of biotech and also the list-based definitions or in other words the classification of biotech will be helpful to show how wide biotech is. Figure 2.1 shows the inter diciplinary nature of biotechnology[3]

[3] See Annex 2 for the main areas of application of biotechnology.



Source: Smith, John E. (1997). *Biotechnology*. Third Edition, United Kingdom: Cambridge University Press

Figure 2.1. The Interdisciplinary Nature of Biotechnology

2.1.2. Statistical Definition of Biotechnology

Beside conceptual definitions of biotech also statistical definition can be made to compare the usage of biotech in different countries. The only source for a statistical definition of biotech is Organisation for Economic Co-operation and Development (OECD) Science, Technology and Industry Working Papers, including member and observer countries. A second edition published by OECD in November 2003 which is updated version of the first edition in 2001 by Brigidte van Beuzekom. In this working paper statistics widely depend on official data rather than private unofficial providers (Ernest & Young, Arthur Anderson) that used in the first edition. Data in this new Working Paper are

presented on a country-by-country basis and the objective is to collect comparable statistics in OECD countries with using a model survey on biotech use and development. However, available biotech statistics are not still harmonised and differ country to country. Thus, to reduce the ambiguity in biotech, maybe new versions come up.

In the earlier papers, definition of biotech varies across countries, depending on the interests of the countries [4]. In some of the countries biotech finds its meaning in a scientific manner, on the other hand some of the countries cites its industrial usage and classify biotech rather than a single definition.

After the Annual Ad Hoc meetings of National Experts on Science and Technology Indicators in March 2000, nations agreed on one statistical definition in 2001 and after the fourth annual meeting of experts member and observer countries agreed on the provisional single definition of biotech and it is;

> *"The application of Science & Technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services." (Devlin, 2003)*

The (indicative, not exhaustive) list of biotechnologies as an interpretative guideline to this single definition is:

> *"• DNA (the coding): genomics, pharmaco-genetics, gene probes, DNA sequencing/synthesis/amplification, genetic engineering.*
> *• Proteins and molecules (the functional blocks): protein/peptide sequencing/synthesis, lipid/protein, glyco-engineering, proteomics, hormones, and growth factors, cell receptors/signalling/pheromones.*
> *• Cell and tissue culture and engineering: cell/tissue culture, tissue engineering, hybridisation, cellular fusion, vaccine/immune stimulants, embryo manipulation.*
> *• Process biotechnologies: bioreactors, fermentation, bioprocessing, bioleaching, bio-pulping, bio-bleaching, biodesulphurization, bioremediation, and biofiltration.*
> *• Sub-cellular organisms: gene therapy, viral vectors.*
> *• Other" (Devlin, 2003)*

2.1.3. Classifications of Biotechnology

Table 2.2 shows one type of classification of biotechnology in Canada which is a result of ad hoc survey of Statistics Canada. There are different types of classifications used by different countries but they are close to each other with some nuances.

[4] See Annex 3 for definition list of biotechnology in OECD member and observer states.

Table 2.2. Industrial Classification of Biotechnology Used in Canada

Category: Human Health - Bio	**Category: Food Processing**	**Category: Forest Products**
1. Diagnostics (e.g. immunodiagnostics, gene probes, biosensors)	9. Bioprocessing (e.g. using enzymes and bacteria culture)	16. Silviculture (e.g. ectomycorrhizae, tissue culture, somatic embryogenesis, genetic markers, genetic engineering)
2. Therapeutics (e.g. vaccines, immune stimulants, Biopharmaceuticals, rational drug design, drug delivery, combinatorial chemistry)	10 Functional Foods/Nutriceuticals (e.g. probiotics, unsaturated fatty acids)	17. (Cleaner) Industrial Bioprocessing (e.g. biopulping, biobleaching, biological prevention of sapstain)
3. Gene Therapy (e.g. gene identification, gene constructs, gene delivery)	**Category: Aquaculture**	**Category: Environment**
Category: Bioinformatics	11. Fish health (e.g. diagnostics, therapeutics)	18. Biofiltration (e.g. treatment of organic emissions to air/water)
4. Genomics and Molecular Modelling (e.g. DNA/RNA/protein sequencing & databases for humans,plants, animals and microorganisms)	12. Broodstock genetics (e.g. tracking superior traits, genetic modification / engineering)	19. Bioremediation and Phytoremediation (e.g. cleanup of toxic waste sites using microorganisms)
Category: Ag-bio	13. Bioextraction (e.g. karageenan from seaweed, antifreeze proteins from fish, flavours)	20. Diagnostics (e.g. detection of toxic substances using bioindicators, biosensors, immunodiagnostics)
5. Plant Biotechnology (e.g. tissue culture, embryogenesis, genetic markers, genetic engineering)	**Category: Mining/Energy /Petrolium/Chemistry**	**Category: Other**
6. Animal Biotechnology (e.g. diagnostics,therapeutics, embryo transplantation, genetic markers, genetic engineering)	14. Microbiologically enhanced petroleum/mineral recovery	21. Custom synthesis- chemical or biological (e.g. peptides, proteins, nucleotides, hormones, growth factors, biochemicals
7. Biofertilizers/Biopesticides/ Bioherbicides/Biological Feed Additives/Microbial pest control (e.g. bacteria, fungi, yeasts)	15. (Cleaner) Industrial Bioprocessing (e.g. biodesulphurization, bio-cracking, biorecovery)	22. Other (please specify)
8. Non-Food Applications of Agricultural Products (e.g. fuels, lubricants,commodity and fine chemical feedstocks, cosmetics)		

Source: van Beuzekom, Bridget (2000). Biotechnology Statistics in OECD Member Countries: An Inventory. Paris: OECD DSTI/DOC (2000) 6

This classification would be helpful to understand the common application areas of biotech. The reason why the U.S. or the E.U. based classification not chosen here is due to the lack of broader classification. In any case, although there is no written industrial classification for both of them, industrial usage of biotech is the same as cited above.

2.2. Biological Diversity Conservation

Biological diversity or biodiversity, defined in the Convention on Biological Diversity (CBD) as:

> *"the variability among living organisms from all sources including, inter alia, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes genetic diversity, and diversity within species, between species and of ecosystems."(the Convention on Biological Diversity, 1992, Article 2)*

Levels of biodiversity can change such as genetic diversity and ecological diversity. Rochini (Acharya, 1999) defined these two as;

> *"Genetic diversity is diversity at the most micro level and refers to variability within and between populations of species. It can be measured in terms of differences between DNA sequences for example. Ecological diversity refers to the variation between species within a certain geographical area or ecosystem[5]."*

Biodiversity and its conservation are important for biotech because biological resources are the key input of biotechnology and it benefits from and makes use of the world's biological diversity, thus biotech affected directly by the erosion of biodiversity. Factors that cause and increase the erosion, are also the factors that directly have adverse effects on biotech and further developments in this field. One of the factors that cause biodiversity erosion is destruction of habitats[6] as the primary cause of species loss and so biological resources[7] like animals, plants, microorganisms and thereof. Whilst destruction of habitats results with biodiversity depletion and human population growth and the uncontrolled economic development seem to be the reason of annihilation of these habitats (Coughlin, 1993). Beside increasing human population growth and uncontrolled economic development there are also other factors with adverse effects to biodiversity, too. The first one indeed is a consequent rather than a direct factor of the biodiversity erosion. Loss of

[5] According to Article 2 of the CBD, ecosystem means "a dynamic complex of plant, animal and micro-organism communities and their non-living environment interacting as a functional unit."
[6] Article 2 of the CBD defined the term "habitat" as "the place or type of site where an organism or population naturally occurs"
[7] Article 2 of the CBD defined the term "biological resources" as "includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value for humanity"

the species have spillover effect because of the interdependence between the species. The impact of extinction will be felt on both directly and indirectly dependent species and this spillover effect continue with radical environmental changes (Acharya, 1999). Secondly, the market failure and government policies have adverse effects on biodiversity, too. Biological resources also called as the "heritage of mankind" are in fact a public good and this means that market prices based on private value, do not accurately reflect its true value to society which refers to 'market failure'(Acharya, 1999). Rochini cites this as;

> *"While economic values for biological resources may exist, based on their immediate use , no value is placed on the depletion of biodiversiyt."*

Government policies that directly or indirectly have negative impacts on biodiveristy and the functioning of ecosystems such as price controls, subsidies in agriculture, energy, water, transport policies, fail to close the gap between the value of biodiversity to private users and it is value to society (Acharya, 1999).

To eliminate or at least to reduce adverse effects of erosion factors discussed above, conservation seems to be the only solution. Maybe before laying out conservation efforts, in general, information about the value of biodiversity from many aspects (environmental and scientific) will be helpful and in particular, info about the value of microbial diversity can help to understand the importance of effective conservation from the side of biotechnology.

2.2.1. The Value of Biological Diversity

According to data from United Nations Environment Programme (UNEP)-World Conservation Monitoring Centre (WCMC) the total number of species has recently been estimated as 14 million and this is not certain enough because of the lack of information about the number of insect, nematode, bacteria and fungus species (UNEP-WCMC, 2000). Swanson gives a ratio that around 40 of 5000 or so plant species screened for their medical value, are in use in prescription drugs (Swanson, 1997).

In August 9-14, 1998, in Canada, Halifax, the Eighth International Symposium on Microbial Ecology that sponsored by the E.U. Directorate-General (DG) XII and Organisation of the American States Health was done. One of the workshops done at this symposium was World Federation For Culture Collections (WFCC) Workshop, about the economic value of microbial genetic resources. This workshop brought together microbiologists, economists and culture collection experts and the reports published after this symposium gives information about the economic values of microbial genetic resources.

From one of the sessions taken in that workshop, James T. Staley (Staley, 1998) from U.S cited general functions and role of microorganisms as:

> *"Microorganisms were the original living organisms on Earth and their biogeochemical activities have sustained the biosphere for about 4 Ga (10^9 years). Thus, microbial life 'set the table' for all subsequent life forms which evolved from them. Atmospheric oxygen produced by cyanobacteria with its accompanying protective layer of ozone which reduced the effects of damaging ultra violet radiation enabled the evolution of land plants and animals. Microbial activities continue to play important roles in the biochemical cycles of carbon, nitrogen and sulfur and other elements enabling ecosystems to recycle these substances into utilizable forms for all living organisms. Agriculture, forestry, and fisheries are examples for commercial activities that are dependent on and sustained by these basic microbial activities. Waste water and solid waste treatment and bioremediation are other examples of the use of microorganisms to transform animal, plant and industrial wastes into non-toxic, utilizable materials. In addition, the vast genetic diversity of microbial life has provided a resource for pharmaceutical and biotechnology industries[8]."*

Beside the examples given above, microorganisms and thereof are source tissue of many industrial materials like industrial enzymes or industrial chemicals in food and drink industry, textiles, paper manifacture, detergent industry, the flavour and fragrance industry, oil production and processing, microbialogical desulphurisation of coal and etc.

J.C. Hunter-Cevera (Hunter-Cevera, 1998) from U.S. cited the value of microbial resources from the point of biotechnological applications as;

> *"Microorganisms have been employed by industrial microbiologists (biotechnologists) to produce products and processes that improve our health, our food and environment. The true value of microbial diversity includes not only the diversity with respect to species richness but also the direct and indirect economic value of profits resulting from commercialization of microbial metabolic products and processes."*

[8] Although the term "biotechnology industries" used in this argument (there are other arguments that used this term) there is not such an industry. There are industries that uses biotechnology during at any level of their production process. i.e food industry, production of cheese, biotech used at the fermentation level of cheese production process.

Erko Stackebrandt from Germany defined the value of microorganisms ecologically, scientifically and commercially (Stackebrandt, 1998). Briefly the ecological value of a microorganism (microbial strain or cells thereof) refers to its function in an ecosystem and the economic value of a non-isolated cell may be nothing but ecologically and scientifically its value would be high once its function in the environment has been elucidated. Scientifically a strain can increase knowledge about history, presence and predictable future of life. He continues with the commercial value of microorganisms and adds that; "…each level of information (DNA-RNA-proteins) is a target for commercial interests". According to him; "the economic value of a strain is defined by present goals of the biotech industry and the degree of exploitation of strains, genetic material or gene products."

Stackebrandt gives some numbers according to some stage-by-stage calculation about how economic value is added to a strain if a strain has no obvious commercial value in its environment. After isolation, deposition and taxonomic analysis done for a strain Stackebrandt assumes its value approximately ECU 10.000 (after isolation and long term deposition in a collection the preparation of 20 ampoulse – German Collection of Microorganisms and Cell Cultures (DSMZ) standard – per strain amount to approximately DM 400 – ECU 200, USD 220 – and after taxonomic analysis approx. ECU 10 000)

Anthony Artuso finds the total value of microbial life forms to the human race immeasurable. But he claims that before valuation of biological resources there are questions that biologists and ecologists must answer because there is still little knowledge about the role of microorganisms in ecosystems (Artuso, 1998). According to him;

> *"Even assuming we have adequate understanding of the essential biological and ecological processes, policy relevant valuation of potential losses in ecosystem services due to disruption of microbial processes can not be accomplished simply by estimating the dollar value of crop losses or other damages that would occur."*

He emphasizes the adverse effects of destruction of habitats with one difference. According to Artuso the policy issue should be expanding the knowledge of microbial diversity, collecting new samples and increase the size of culture collections rather than so much conservation. His attitude can be summerized as;

> *"However, given the numerous commercial uses of microbial organisms, a strong argument can be made for economic analysis of the benefits of microbial research, from sampling and collection through curation and biochemical and genetic evaluation."*

2.2.2. Conservation of Biodiversity and International Agreements

Erosion of biodiversity is not a new problem, thus, up to date there was several efforts to reduce the destruction of habitats, extiction of species and erosion of biodiversity. There are some conventions related with conservation of species in particular like the World Heritage Convention (WHC), the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES), the International Plant Protection Convention (IPPC), the Ramsar Convention, the Bonn Convention. For example, the Ramsar Convention on Wetlands of International Importance was signed in 1971 is an intergovernmental treaty which provides the framework for national action and international cooperation for the conservation and wise use of wetlands and their resources. There are presently 138 Contracting Parties to the Convention, with 1367 wetland sites, totaling 120.5 million hectares, designated for inclusion in the Ramsar List of Wetlands of International Importance. CITES, signed in 1975, ensures that international trade in these resources with 166 Parties now. IPPC is an international treaty whose purpose is to secure a common and effective action to prevent the spread and introduction of pests of plants and plant products, and to promote appropriate measures for their control.

After 1987 the term "sustainable development" become to be articulated beside conservation. The Brundtland Report of the World Commission on Environment and Development in 1987 defined the term 'sustainable development' and it is defined as "meeting the needs of the present generation without compromising the needs of future generations" (Coughlin, 1997). This term became the theme of the United Nations Conference on Environment and Development (UNCED) held at Rio de Janerio in June 1992, also known as the Earth Summit, involved over 100 Heads of State and Government, representatives from 178 countries, and some 17,000 participants. One of the key agreements adopted at Rio was the CBD and it was the first agreement that covers all the living forms for conservation, sustainable use and the fair and equitable sharing of the benefits from the use of genetic resources.

The CBD which entered into force on 29 December 1993 is an environmental treaty but also it is the treaty which refers to biotechnology first. Article 1 sets the objectives of the Convention:

> *"Article 1. Objectives:*
> *The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resourcesand by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding."*

Article 6 of the Convention sets on general measures for conservation and sustainable use[9]:

> *"Article 6. General Measures for Conservation and Sustainable Use*
>
> *Each Contracting Party shall, in accordance with its particular conditions and capabilities:*
>
> *(a) Develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity or adapt for this purpose existing strategies, plans or programmes which shall reflect, inter alia, the measures set out in this Convention relevant to the Contracting Party concerned; and (b) Integrate, as far as possible and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies."*

What makes this Convention different from others is its more comprehensive approach about biodiversity. Whilst other conventions have specific nature, the CBD can be called as an umbrella convention in terms of biodiversity conservation because it comprimises the conservation and sustainable use of any biological resource. According to C. Takase, the CBD secretariat in 1998 (Coughlin, 1993);

> *" The CBD adopts the ecosystem approach in order to ensure the consideration of the essential processes and interactions amongst organisms and their environment."*

Modern biotechnology with new tools and techniques provide better methods for conserving biological diversity, both for the immediate use of the biotechnology industry and also for the long-term sustainability of ecosystems. These methods can be classified into two groups. First one is the *"In situ"* conservation as an optimal method because biological resources can be conserved better within the ecosystem that they originally come from. (Acharya, 1999). It is defined in the CBD in Article 2 as;

[9] Sustainable use defined as "the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations." in ART. 2 of the Convention

"the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties."

Beside its definition, provisions about *in situ* conservation are mentioned in Article 8 of the CBD. Article 8 envisages functional measures for protected areas, endangered species, regulative measures for protection of biological resources and cooperation for financial support in *in situ* conservation.

When *in situ* conservation is not available the second best choice is "*ex situ"* conservation. According to Article 2 of the Convention;

"Ex-situ conservation means the conservation of components of biological diversity outside their natural habitats."

Article 9 of the Convention sets out the provisions for *ex situ* conservation and it envisages regulative measures for *ex situ* conservation, highlights the importance of collections for biological resources with financial support for *ex situ* conservation effort of in developing countries. From this point of view another important policy area appears related with biodiversity, it is biological resource centers that are main providers of biological resources.

2.2.3. Biological Resource Centers (BRCs) and Culture Collections

As Artusto (1998) mentioned, conservation is not the only policy issue about biological diversity. For further research and development in both scientific and industrial manner, for sustainable use and effective conservation of biological resource, to understand the function of microorganisms in ecosystems and for more information about biological resources, collecting new samples and precence of biological resource centers like culture collections as providers of these samples are also needed. In general biological resource centers and in particular culture collections are an essential part of the infrastructure underpinning life sciences and biotechnology and they are providers of

services and new methods as ex situ conservatories. Because of these reasons they are the main part of agenda settings in policy making processes as much as conservation activities.

Indeed the term "biological resource center' may be newly used in the meaning of providers of new methods for conservation, identification and other related services but traditional methods have been used for about centuries because conservation of biological material is not a new phenomenon. Rochini (1999) gives examples to traditional conservation and prospecting activities;

> *"In the quest to improve variety in the food we eat and in its productivity, botanists have traveled widely to bring back interesting species to native lands. Latin America, for example, gave the world important crops such as potatoes and maize, while centers of crop diversity in Asia provided the world with varieties of wheat. Thus biodiversity poor regions such as Europe initially attempted to improve genetic diversity by introducing new varieties found in various parts of their colonies. One prime example of this is the spice trade that developed in the 15th and 16th centuries, carrying plants and seeds between south east Asia and Europe, via India and Africa. Other countries where collection has played an important role include the U.S. and the erstwhile USSR, both of which played important roles in identifying and conserving genetic diversity and regions of rich diversity.*
> *As trade with the colonies increased, they later housed a large variety of species which originated in these colonies and survived the long voyage back home. Kew Gardens on the outskirts of London, for example, used resources from the Government to develop its vast collections of exotic plants. In the U.S.A., the navy was deployed to carry out missions to other countries and to ship back exotic plants to U.S. Seed collections were regularly deposited in botanic gardens before the emergence of seed banks and agricultural research stations."*

a. Biological Resource Centers

OECD published a report under the title "Biological Resource Centers: Underpinning the Future of Life Sciences and Biotechnology" in 2001 (OECD, 2001) which published two years after the "OECD Workshop Tokyo '99 on Scientific and Technological Infrastructure" to identify "the policy, orginisational and economic challenges faced by BRCs and makes recommendations to governments for national and international solutions." It cites the CBD's role from BRCs point of view as;

> *"the CBD highlighted the need for comprehensive scientific study of biological diversity and raised the importance of Biological Resource Centers (BRCs) in the eyes of governments and the scientific community."*

Definition of BRCs based on the one adopted at the 1999 Tokyo Workshop is mentioned as (OECD, 2001);

> *"They consist of service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems.*

BRCs contain collections of culturable organisms (e.g. microorganisms, plant, animal and human cells), replicable part of these (e.g. genomes, plasmids, viruses, cDNAs), viable but not yet culturable organisms, cells and tissues, as well as databases containing molecular, physiological and structural information relevant to these collections and related bioinformatics."

This report provides comprehensive information about biological resource centers from many aspects There are questions under every subtitle which points out specific issues about BRCs with related case studies. First of all, the report seeks answers of the need for BRCs:

1. Why are BRCs needed?
2. What are their essential functions?
3. Why should governments and private sector care about them and take steps to ensure their suvival?
4. Why are the current reprositories of biological resources, including ex situ culture collections of microorganisms and other living cells, housed in many countries in institutions that are often not connected to each other and are inadequate to meet the world's needs for biological resources?

The answers to these questions are explained by laying out the role of BRCs from many aspects. Role of BRCs listed in the OECD Report (2001) as;

i. Preservation and provision of biological resources for scientific, industrial, agricultural, environmental and medical R&D and applications[10]: BRCs serve an essential infrastructural function for scientific investigation and R&D therefore experiments performed in one laboratory by one set of investigators must be replicable in another laboratory and results must be reliable. BRCs are also essential sources of information and materials for industrial and many other practical uses. BRCs provide the genetic elements, organisms and information used in biotechnological, agricultural, environmental and medical applications. Without them, every user would have to "reinvent the wheel" and invest innurable hours in the costly recovery of organisms and genes and their characterization.

[10] Headings are quoted from the same report of OECD; Underpinning the Future of Life Sciences and Biotechnology (OECD, 2001)

ii. Performance of R&D on these biological resources: They contribute the advancements of the life sciences and biotechnology by their expertise in identification, characterization and preservation of biological resources.

iii. Conservation of biodiversity: All kinds of BRCs (culture collections, viral reprositories, herbaria, botanical gardens, zoos and *ex situ* plant and animal genetic resource collections, seed and gene banks) help preserve biodiversity, which is threatened by the factors that cause erosion of biodiversity. The CBD also highlights the need for BRCs as *ex situ* conservatories of biodiversity.

iv. Repositories of biological resources for protection of intellectual property: Collections called as "International Depository Authorities (IDAs) " maintain secrecy about the deposited resources and by this way serve as legally mandated repositories of biological resources.

v. Resources for public information and policy formulation: According to the OECD Report;

> *"BRCs provide essential expertise for formulation of government policies on biological resources and for information and assurance to the public. They can thus serve as an important interface between government, industry and the public and can help the public understand the value of conserving biological resources. They are bodies which the public and policy makers can call upon for objective help in developing regulations and guidelines for the safe and ethical use of biological resources, including those derived from human genes. ….Much assistance from BRCs will be needed to develop and implement policies on the uses of biological resources in the age of molecular biology heralded by the genomics revolution."*

There are other important subjects related with BRCs like legal status of biological resources and role of BRCs from this side, financial support for BRCs, global network of BRCs, quality and expertise of BRCs. Although all of them important financial support for long term stability play a key role for effective functioning of BRCs. To ensure long term stability BRCs requires adequate and reliable sources of funding. Questions asked in the Report are;

a. How much core support must come from governments?
b. How can other sectors contribute to the functioning of BRCs? c
c. What models of funding or partnerships can be used to ensure the sustainability of national BRCs?

d. Can costs be lowered through international co-operation?
e. Is there a threat that some valuable biological resources will be lost to the global community owing to lack of funding?

All of these questions are important from the side of governments because as biological resources are main raw materials of biotechnology activities in any field (industrial, agricultural or pharmaceutical), sustainability of BRCs as the main providers of these biological resources is necessary to keep up with recent advancements in biotechnology. The Report also underlies a serious problem about establishing a network between "orphan collections" (collections that are in risk due to lack of quality) and high-quality BRCs because "if BRCs reach an agreement to form a network aimed at eliminating duplication and sharing biological resources should one of the members or nodes in that network fail for lack of support".

A calculation made in the report akin to Stackebrandt's calculation, but this time costs of a BRC to add a culture to its collection is calculated rather than the ultimate value of that culture at the end of all stages like isolation, deposition and taxonomic analysis. DSMZ estimates that it costs USD 2 500-3 000 to add a bacterial culture to its collection. The American Type Culture Collection (ATCC) estimates that it costs between USD 5 000 and USD 10 000 (depending on the type and quality of the material-tissue cultures, organisms, databases, etc.) to add new items to its collection when the costs of quality control, validation, long-term preservation and global distribution are taken into account.

In the absence of a functioning financial mechanism it seems hard to provide sustainability for BRCs. Solutions for this problem varies because there is no single system for funding these centers. One solution for this problem is charging fees to obtain biological materials and to access associated databases. This is underlined in the Report as (OECD, 2001);

> *"Varying fee structures can be applied for access depending on the nature of the biological material (microbial, plant or animal resources), the status and constraints of the institution holding the resources and its relationshipwith the public and private sectors, national policies and relevant internationalframeworks. Varying fee structures and appropriate material transfer agreements can allow for the inclusion of private industrial collections of biological resources into a co-operative system of BRCs."*

Other sources of financial support listed in the Report as; government support, private industrial support for or participation in the functioning of BRCs, private industrial support

for internal restricted BRCs, public and private foundation support, public fundraising, sale of biological resources and technical materials, provision of specialist services and technical consulting expertise, research income (e.g. grants and contracts), fees for repository services (e.g. for patent strain maintenance and safe deposits), provision of technical courses.

To meet the challenges of financing BRCs some suggestion made at the Report. Co-ordination of BRCs, developing marketable products and services as long as they do not diverst capacity from the core activities of BRCs, charging fees that are affordable for users and harmonising fee structures for example. But inevitably the role of governments and private sector or role of industries can not be ignored because when funding is in consider, support of these actors is a determining factor. As mentioned before there is no single model for financing BRCs therefore any combination that encourages high standards of quality, promote research, development, technology transfer and commercial exploitation will be a successful model. There are two examples for this, one is Germany's DSMZ and the other is ATTC. ATTC recieves only 9% of its budget from the United States government and DSMZ recieves about 80% of its budget from the government and only about 20% from sales of materials and services. However government funding is emphisized at the Report by this words;

> *"While a uniform structure of funding is not critical, considering the different situation of public-private relations with regard to conservation and utilisation of diverse biological resources, most BRCs will require a significant government funding component, and some guarantee of continuing funding to ensure that their essential functions remain reliable for R&D and support of biotechnology."*

b. Culture Collections

Everything stated for BRCs are also valid for culture collections. So what left to say about culture collections is some technical information about them. What makes culture collections more crucial than other types of BRCs is they are the main source of microbial resource supply.

As mentioned before the value of microbial resources is very important for biotechnological developments. A. Malik Khursheed emphisizes the importance of culture

collections in a technical information sheet of World Federation for Culture Collections (WFCC) referred to microbial resources as ;

> *"The use of microorganisms and cell cultures to solve agricultural, food, health, energy and environmental problems has considerably increased world wide. Similarly one of the priority of the developing world is the production of food and energy through the development of agriculture and biotechnology. For all this, there is an ever growing need for a constant source of supply of microorganism and germ-plasm....Consequently, there is a growing awareness for the value of microbial culture collections in the conservation of genetic resources and biodiversity in both the developed and the developing world."*

Vanderlei Canhos cited the importance of culture collections with refer to the CBD in WFCC Guideline[11] for culture collections as;

> *"The increasing demands on culture collections for authenticated, reliable biological material and associated information have paralled the growth of biotechnology. More recently, worlwide recognition of the need to conserve the microbial gene pool for future study and exploitation by mankind has highlighted the centers of expertise in culture isolation, maintenance, identification and taxonomy. The Convention on Biological Diversity places additional demands on culture collections in terms of conservation and capacity building."*

Main tasks of these collections with refer to WFCC Guideline, are preservation of cultures, documentation of and computerisation of cultures to establish useful ecological, medical, genetical and biochemical data[12], patent deposits includes identification, culture supply for industrial and scientific use, printing catalogues of the strains available for distribution, training staff and any consultancy about these activities. Culture collections are responsible from these tasks and other technical tasks related to those cited above both nationally and internationally in some cases. According to their tasks it can be said that culture collections are active agents of capacity building in the field of biotech and because of these reasons they are also one of the main subject that take attention of policy-makers.

[11] This guideline is the second edition of the only internationally approved guideline covering all aspects of culture collection activity.

[12] More specifically; information about geographic location, substrate or host, date of isolation, depositor, name of the person isolating the strain and identifying the strain, preservation procedures, any regulatory conditions applying, e.g., quarantine, containment levels, patent status.

2.2.4. Key Actors in Conservation of Biodiversity

Beside the positive role of biotech in conservation and sustainable use of biodiversity and the value of biodiversity for further developments in biotech, a more deepen relation also exists between them. This relation is set on a formulation of a mechanism which let the key actors to accomplish their common goal with different motives. Different kinds of classifications can be made for key actors in this mechanism such as the South and the North, the guardians and the exploiters, the conservationists and the biotechnologists. But these actors have the same objective at the first place and this is conservation and sustainable use of biological resources.

Distribution of biological diversity is not the same on the Earth therefore a geographical distinction appears between the South and the North. The South is composed of developing countries which are rich in biological diversity but do not have sufficient resource (technology) to conserve and exploit from these diversity. The North is composed of industrial countries which is sufficient enough to exploit from these resources commercially but poor in biodiversity. This distinction is made in almost every argument and generally taken as an irony what also makes the relation of biodiversity and biotech conflictual. This side of their relation is more relevant with intellectual property rights issue because sovereignty rights of biological resource owner countries as well as fair and equitable sharing of the benefits arising out of the utilization of these resources adds another dimension to debates. But here the concerning subject is although the South is rich in biological diversity, they can not easily take advantage of this situation. Advantage of developing countries turn into be the advantage of industrialised country based companies by regional differences in terms of development.

As mentioned before when conservation and sustainable use of biological resources is in consider the CBD should be taken into account in the first place. It sets out a multilateral approach and its provisions are binding for both industrialized and developing countries. It has been seen to be an appropriate solution for conservation and sustainable use phenomenon, but from its signing date to today attitudes of the parties did not stay the

same. Rochini (1999) described the changes from developing countries and related industries point of view as:

> *"Nonetheless, as the importance of biological diversity both in conservation and as a raw material for scientific research becomes more recognised, it is clear that attitudes in the developing countries and among industrialists have chandged dramatically over the years. Developing countries have tended to become increasingly aware about the importance of biological diversity as an input into the pharmaceutical industry or for agricultural productivity. They have shown increased interest in exploiting biodiversity for its value added content, i.e., the knowledge contained in biological material and the contribution it can make to new medicines and new plant varieties, and in conserving it for the very same reasons.*
> *On their part, pharmaceutical, ag-bio and chemical companies, which are the dominant users of biodiversity, are realising and acknowledging the contribution made by genetic resources to their past and present research and the need to ensure its sustainable use for it to contribute significantly to their future research as well."*

As understood from Rochini's words, the dominant users, generally they are industrialised country based companies, can be called as the exploiters. It is the exploiters who possess the scientific and technological capabilities to develop value added products from raw biological materials and it is the guardians of biodiversity who appear to be expected to invest in the conservation of the raw material(Rochini, 1999). Formulation of a mechanism which mutually interacts the key actors with different motives is issued more detailed in the intellectual property related topics from many different aspects.

2.3. Biotech Policies From The Side of Intellectual Property Rights Issues

The role of intellectual property rights (IPRs) in international trade has grown considerably by the advances in information and communications technologies and the life-sciences including biotechnology. IPR protection in the field of biotech generally taken into account in many arguments from the side of international agreements such as the CBD and the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). The relationship between TRIPs and the CBD has become a major focus of discussion in international policy circles.

The CBD which entered into force on 29 December 1993 is an environmental treaty and aims to secure the conservation and sustainable use of biological diversity. TRIPs, which is signed at the end of the General Agreement on Tariffs and Trade (GATT) Uruguay Round in 1994 and came into force in 1995, sets minimum standards for patents and other IPRs in the 134 World Trade Organisation (WTO) member countries. The complex legal, political and social links between IPRs and the conservation of biodiversity and genetic resources are particular evident in the biotechnology sector. Genetic resources provide a store of knowledge and the raw material for the biotechnology industry. When knowledge and information are turned into a saleable product in a regulated market, individual plants and animals may so be transformed from public to private goods. Thus, balancing private and public interests in intellectual property which before the conclusion of the TRIPs Agreement was the responsibility of only national authorities has become an international concern.

Different views about compatibility of these agreements generally focus on the subjects listed below:

1. Benefit sharing through appropriate transfer of technology
2. Benefit sharing through appropriate access to genetic resources and traditional knowledge
3. Effective *sui generis* system for plant variety protection and patentable subject matter in the context of Article 27.3(b) of TRIPs Agreement

2.3.1. Article 16 of the CBD and Benefit Sharing Through Appropriate Transfer of Technology

The CBD and TRIPs do not refer to each other and neither treaty specifies that it is subject to other. Article 16.5 of the CBD recognises that intellectual property rights "may have an influence on the implementation" of the CBD. It obliges states to cooperate in order to ensure that intellectual property rights are "supportive of and do not run counter to" the objectives of the CBD. At the same time Article 16.2 states that the technology

transfer process is to be consistent with "adequate and effective protection of intellectual property rights". This obligation itself needs to be consistent with Articles 3, 4 and 5. The only technology referred to is biotechnology, though Article 16 is concerned more generally with technolgies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment".

> *"Article 16. Access to and Transfer of technology*
>
> *1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.*
>
> *2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.*
>
> *3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.*
>
> *4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.*
>
> *5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."*

Essentially Article 16 of the CBD preserves the entitlements of intellectual property owners as they are defined in international law such as TRIPs.

Technology transfer is highlighted as a method for acieving one of the CBD's three principal objectives and IPRs identified as a significant aspect of technology transfer.

Article 7 of TRIPs is also underlying the contribution of IPRs to provide a positive environment for investment in the development and transfer of technology.

> *"Article 7:*
> *The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."*

IPR protection can be provided by copyright and related rights, trademarks, geographical indications, industrial designs, patents and etc. One argument is, strong IPRs are a preliminary condition for the international transfer of new technologies, at least those that can easily be copied. The only way companies will feel encouraged to transfer these technologies is if IPR protection is strong enough for them to charge licence fees that reflect the costs of innovation. Patents are one of the effective tools for strong IPRs and it needs to be noted that generally IPRs and particularly the patents are strictly national law; they apply only where IPRs are available and to obtain patent rights, the patent application must be made in each country. D. Miles Gaythwaite (Gaythwaite, 1999) express the expense of the patent applications in each country with respect to this characteristic of patents as;

> *"Patents are distinctly national in character. A patent granted in one country and if the patentee wants protection in a number of countries then, in general, a separate application has to be made in each country in which protection is desired; and usually the applications have to be filed within the 1 year priority period provided for in the Paris Convention. This means that a considerable investment in terms of filing and translation fees has to be made at a very early stage of an invention, before the prior art has been properly explored and perhaps before the actual commercial potential of the invention has been worked out."*

With the granting of the patent , the holder is given the right to exclude for a limited time period but for this monopoly situation, the patentee discloses the details of the invention to the public. Some parts of the world still do not have legally installed patent systems and may attempt to exploit published patents without any financial return to the patentee (Smith, 1997). Companies will be reluctant to transfer technologies that may have cost them millions of dollars to develop to countries where domestic firms can freely adopt the technologies and produce competing goods.

On the other hand, by the patent rights that mutually recognised, patent owners can use their legal rights either to block access to their technolgies or charge licence fees that are too high for domestic firms and this can reinforce North (owners of protected

technology) – South (buyers and suppliers of non-protected, non-trditional techologies such as genetic resources and the knowledge surrounding those resources) inequilities .

2.3.2. Benefit Sharing Through Appropriate Access to Genetic Resources and Traditional Knowledge

The CBD aims to achieve fair and equitable sharing of benefits arising out of the utilization of genetic resources but if there is right to patent such resources, is it possible to achieve this objective? From the IPR supporters point of view, in the absence of intellectual property protection there would be no benefits to share in the first place. The argument is that patents encourage investment in invention and the research and development needed to turn inventions into marketable innovations. On the other hand, in the case of such access to genetic resources of the provider country this may turn out as bioprospecting or what is often referred to as biopiracy. It is not only the biological resources that are screened by the researchers, also traditional knowledge (TK) that includes knowledge related to biodiversity screened. Although the language is somewhat vague, TK take place in the CBD under the Article 8.j and proveked much discussion on the relationship between TK and TRIPs. It requires parties to do three things:

a. respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional life styles relevant for the conservation and sustainable use of bioligical diversity,

b. promote theit widerapplication with the approval and involvement of the holders, and

c. encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

It needs to be noted that although TRIPs offers unprecendented protection to formal innovations (such as the outputs from corporate research laboratories), it offers no formal protection for TK (such as seed varieties improved by generation of farmers , or community-held knowledge of medical applications of plants). In the IISD (International

Institute for Sustainable Development) Trade and Development Brief (IISD, 2003), this is expressed by an example;

> *"…scientists have been able to patent cetain compounds found in a plant called Hoodia, which has traditionally been used by certain groups of San (Bushmen) people as an appetite suppresant. But the indigenous groups that showed the scientists how to use the plant were in no position to assert property claims to this knowledge through the IPRs systems. Arguably, this imbalance is unfair both to the traditional knowledge holders themselves and to those developing countries where the presence of such knowledge could potentially provide competitive advantages for their economies."*

Unfortunately, indigenous people are generally unaware of the value of their knowledge.

Biodiversity prospecting, or bioprospecting, involves the exploration, extraction and screening of biological diversity and indigenous knowledge for commercially valuable genetic and biochemical resources. When the CBD objectives are in consider, bioprospecting could contribute conservation of biodiversity in an economic manner if bioprospectors gave a portion of their profits to the country of origin. But as laid down before, by the legal rights given to the holder of the patent, there would be an imbalance between the provider of the resource (so called mega bio-diverse countries, mostly in Latin America, south-east Asia, Oceania and, to some extent, Africa) and the holder of the patent (mostly the industrialised countries). Also for TK, this gap is widening between the North and the South due to inexistance of a formal protection system as patents.

2.3.3. Effective *Sui Generis* System For Plant Variety Protection And Patentable Subject Matter In The Context of Article 27.3(b) of TRIPs

There is a considerable interaction between the rights referred to in TRIPs and the subject matters of the CBD. The CBD relates with a range of subject matter like technology (defined to include biotechnology) that relates to conservation and sustainable use, biological resources, information from all publicaly available sources that relates to conservation and sustainable use, indigenous and traditional knowledge and technologies (DG Trade European Commission, 2000). These are also subject matter of IPR protection categories found in Part II of TRIPs like patents. In all fields of technology any invention whether products or processes that are new, suitable for industrial application and that

involve an inventive step requires patents. It is obvious that patents are particularly important in the life sciences and biotechnology sector because of the expense of doing research in these fields and the rapid pace of innovation.

The guiding principle of the CBD is that states have sovereign rights and responsibilities with respect to the exploitation of their own resources. The strongest overlap between IPRs and biodiversity related matters is generally Article 27.3(b) of TRIPs which deals with patentable material. One view is TRIPs rules on the scope of patentable material may violate national sovereignty by giving away rights that accorded states under the CBD.

> *"Article 27.*
> *3. Members may also exclude from patentability:*
> *(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."*

While TRIPs allows countries to exclude plants from their patent laws, it requires that countries provide some kind of IPR over plant varieties. One way of this expressed by the "effective *sui generis*" phrase. Because it is unclear what an effective *sui generis* system is or should be, there has been a great deal of discussion as to the meaning of it and it is completely open to interpretation. This is widely interpreted to mean Plant Breeders' Rights as in one of the UPOV (the Union for the Protection of New Varieties of Plants). The UPOV system of plant variety protection came with the adoption of the International Convention for the Protection of New Varieties of Plants by a Diplomatic Conference in Paris on December 2, 1961. It was revised in 1972, 1978 and 1991 and by the year 2005 it has 59 members which 44 of them are mainly industrialised countries. The objective of the Convention is the protection of new varieties of plants by an intellectual property right. In most of the arguments it has been claimed that it is the industrialised countries who argues that the model provided by the UPOV is the best *sui generis* system for now. Most developing countries do not agree, because that model is highly biased toward the commercial interests of industrial breeders in the North and it helps promote genetic uniformity in agriculture. Between these countries, those with high levels of industrial seed production, but low levels of biodiversity and those with high levels of biodiversity,

but lower technological development, there is a difference in the approach to patenting life forms. Industrialised countries are more tended to accept the IPR based systems that support technological value added but what southern countries argue is patent protection on life forms (plant and animals) should be prohibited because corporate monopolies touching peoples' basic needs are dangerous. Ownership rights that patents afford over a plant variety means monopoly rights in the international market.

As required by the TRIPs Agreement the review of Article 27.3(b) began in 1999, issued in Paragraph 19 of the 2001 Doha Decleration and since the semptember 2003 Cancún Ministerial Conference, the TRIPs Council has continued to discuss this issue. But the main issue is not limited only with what an effective *sui generis* system is or should be, also the patentability of biotechnological inventions taking place at the centre of the debates. According to 27.3(b) of TRIPs micro-organisms must be patentable. But the term micro-organism is not clear as the "effective *sui generis* system" phrase. Because of that reason this can include everything from human cell lines, compounds find in animals to plant genetic material in condition of being new, involve an inventive step and being capable of industrial application. So this can let patent protection for resources existing in nature as if they are inventions although they are discoveries.

Patent laws of Europe and North America allow patenting if it is extracted from nature and make it available for industrial utilization for the first time. Changing the substance or life form in some way, such as by adding something to it (e.g.,gene), substracting something from it (purifying it), mixing it with something else to create a new effect, or structurally modifying it so that it differs from what it was before. It is also possible to get a patent on a natural substance by being the first to describe it in the language of biochemistry and then suggesting an industrial application (IISD, 2003). Defenders of non-patentability of life forms claim that like protection of plant varieties by IPRs, granting patents on micro-organisms may violate the sovereign rights of countries, too.

In 2002 the WTO Secretariat published a report (IP/C/W/369) about the review of the provisions of Article 27.3 (b) and the two main sections of discussions in the context of the review of provisions of Article 27.3 (b) are issues relating to the patent provisions of

Article 27.3 (b) and issues relating to the *sui generis* protection of plant varieties. It summurizes the point of different Parties view with refer to their proposals on each subject. According to this report still there is no consensus on neither what the effective *sui generis* system nor patentable subject matter is or should be.

Consequently, especially when patents are in consider with IPRs and biotehnology, there is a common willing between the industrialised countries which are the main exporters of technology. A patent which is valid in every country would cut down all the costs of patent applications, encourage R&D and technology transfer due to restrictions to copying. Which broaden the limits of patentable subject matter and allows plant or animal based inventions be patentable or at least a system provides protection of plant varieties are the desired patent system objectives of these countries. On the other hand, these are also threaten sovereign rights of origin countries which are the providers of genetic resources due to the lack of patent systems of the source country at the national level and lack of valid protection for TK both in national and international level. Conflicts are arising both from the relation between the CBD and the TRIPs and interaction of these two with national legislations. The CBD envisages technology transfer in the context of biodiversity conservation but industrialised countries find it too risky if IPR protection is not harmonised worldwide. Biodiversity rich countries become aware of the value of their biological resources and now they find it risky to allow access to genetic resources because once these resources screened by any agent (governmental or private institutions, universities, firms and etc.) flexible legislations of countries allow patents if modification done to the sample resource, which is also known as biopiracy. These issues seem to be argued in the following years until a more definite rules set for IPR in the field of biotechnology.

2.4. The Politics and Economics of Genetically Modified Organisms

Although genetically modified organisms (GMOs)[13] in agriculture have been available only for a few years, their commercial use is expanding rapidly. As Cyntia Robbins Roth mentioned biotech allows to engineer into crops traits that would never have occured by traditional plant breeding, by introducing genes from one species into another. For example, a gene from a soil microbe called *Bacillus Thuringiensis*[14] has been used to confer pest resistance on a wide variety of plants and by this way crops prosper without the usual attack by insects and worms, without the need for excessive pesticides (Roth, 2000). GMOs can be defined as organisms in which the genetic material (DNA) has been altered in a way that does not ocur naturally by mating or natural recombination. The most common types of GMOs are genetically modified crop plant species and include genetically modified maize, soybean, oil-seed rape and cotton. They have generally been genetically modified to provide resistance to certain insect pests and tolerance to specific herbicides. In summary such biotech applications in agriculture return back to breeders as lower production costs, higher yields and reduced pesticide use. But GMO concept is not limited only with agricultural applications but it can be said that although the term GMO used for all living forms that are modified, generally it refers to trangenic crops.

Much discussion of biotechnology currently focuses on applications of biotech like GMOs. Besides non-market effects of GMOs like environmental and food safety effects, regulatory divergencies between the E.U. and the U.S. are core subjects of the discussions. GMO debate is being conducted impatial groups like private sector, public interest groups like consumer groups and environmental groups, government agencies and scientists who believe strongly in their positions.

[13] Living modified organisms (LMOs), and transgenic organisms are other terms often used in place of GMOs.
[14] Bacillus thuringiensis (Bt) is a soil bacterium that produces toxins against insects (mainly in the genera Lepidoptera, Diptera and Coleoptera). Bt preparations are used in organic farming as an insecticide.

2.4.1. Non-market Effects of GMOs and Biosafety

Biosafety is,

> *"the safe development of biotech products and their safe application resulting from the existance of mechanisms for the safeguard of human and animal health, safe agricultural production, safe industrial production, safeguard of the natural plant and animal species and the environment from negative consequences from the practice and applications of biotechnology and its products (Gopo, 2001)."*

What people who opposed to GMOs underlines from an environmental perspective is the risks of altered genes migrating into non-crop plants (gene escape) and the risks of pests, such as insects and viruses, developing a resistance to genetically modified plant pesticides (Fischer, 1998). On the other hand, according to supporters of GMOs under the assumption that there is no approved risk of GMOs, there are economic and other benefits for the producer and the end user. Decreased use of conventional pesticides will result in substantial health benefits for farm workers, both human and non-human, will benefit through enhanced air and water quality, herbicide tolerant plants have a positive impact on crop management practices, production and equipment costs go down, increase in food production in third world countries are some of the benefits which the supporters defend (NABC, 1998).

Because of environmental, food safety and ethical concerns with the production and use of transgenic crops have been voiced effectively that these lead to negotiation of a Biosafety Protocol or as it called the Cartagena Protocol. It is a protocol of the CBD, Article 19.3 of which provides for Parties to consider the need for and modalities of a protocol on the safe transfer, handling and use of living modified organisms (LMOs)[15] that may have an adverse effect on biodiversity, taking also into account risks to human health. The Protocol came into force on 11th September 2003 after the 90th day since its ratification by the 50th country. The Biosafety Protocol is an environmental agreement and does not address food safety. Food safety is addressed by other international fora. To establish and enforce rules regarding the application of food safety, the Sanitary and

[15] According to Biosafety Protocol LMO is any living organism that possesses a novel combination of genetic material obtained through modern biotechnology. A living organism is biological entity capable of transferring or replicating genetic material.

Phytosanitary (SPS) Agreement of the WTO permits countries to take legitimate measures to protect the life and health of consumers as well as animals and plants.

The Cartagena Protocol creates an advance informed agreement (AIA) procedure that in effect requires exporters to seek consent from importers before the first shipment of LMOs meant to be introduced into the environment (such as seeds for planting, fish for release, and microorganisms for fertilizing and bioremediation). It requires bulk shipments of LMO commodities, such as corn or soybeans that are intended to be used as food, feed or for processing, to be accompanied by documentation stating that such shipments "may contain" living modified organisms and are "not intended for intentional introduction into the environment." It includes a "savings clause" that makes clear the Parties' intent that the agreement does not alter the rights and obligations of governments under the WTO or other existing international agreements. It does not require consumer product labeling which is a considerable issue which is at the centre of debates. The mandate of the Protocol is to address potential risks to biodiversity that may be presented by living modified organisms and issues related to consumer preference were not part of the Protocol negotiation.

In terms of non-market effects of GMOs, they can include human health and environmental risks as side effects. As Kathen (2000) mentioned human health risks can include allerginicity, toxicity of GMOs and antibiotic resistance. Environmental risks can include as mentioned by Nelson and De Pinto (2000), “resistance development in target and nontarget populations, the possibility that the plant might become a weed, flow of the novel genetic material to other species and loss of antibiotic effectiveness”. But it should be noted that both positive and negative side-effects of GMOs are hypothetical and that is why legal measurements for biosafety depends on national regulations rather than international regulations due to different interpretations for precautionary principle and different risk assessment approaches.

2.4.2. Legislation of GMOs

a. Elements of GMO Regulations

Related issues of GMOs in a regulatory framework can be divided into three parts, the first one is product-based vs. process-based regulatory approach of different countries, risk assessment issues and labelling.

As mentioned at 6th International ICABR (International Consortium on Agricultural Biotechnology Research) Conference product-based regulatory approach reflects the U.S. and Canada policy responses and according to this the focus is on determining the safety of the product in question, rather than on the process by which it was produced (Hobbs, Gaisford, Isaac, Kerr and Klein, 2002). "Genetically modified food products that are deemed susbstantially equivalent are subject to the same set of health and safety and approval regulations as conventional foods" and "to determine substantial equivalence, genetically modified products are judged alonside similar non-genetically modified products" (Hobbs, Gaisford, Isaac, Kerr and Klein, 2002). In the same conference notes, the E.U.'s position explained by process-based approach. According to this approach if the food is genetically modified an entirely seperate set of regulations applies and a manufacturer or importer must show that commercialization of the genetically modified food does not pose a risk to human health or to the environment and by this way the process by which the food produced becomes important.

Second issue which makes the E.U's approach different from the U.S.' approach is the risk assessment procedures. According to the E.U.'s regulatory framework with refer to precautionary principle the E.U. not approve genetically modified products until it can be proved conclusively that they are safe (Perkis, 2000). The precautionary principle is one of the issues in dispute of international law. It is designed to promote environmental protection by excluding scientific uncertainty as a justification for delaying action in the face of potentially serious threats to the environment. The most well-known example of

the precautionary principle in its general form is that contained in Principle 19 of the Rio Declaration which states,

> *"States shall provide prior and timely notification and relevant information to potentially affected States on activities that may have a significant adverse transboundary environmental effect and shall consult with those States at an early stage and in good faith."*

The precautionary principle is essentially a risk assessment tool and countries differ on how to reflect precautionary measures in public policy. Some of them argue that precautionary measures that allow policy action should be taken in the absence of full scientific certainty and others claim that if the products safety is not proven in a scientificly this is suufficient for restriction of trade in products that pose a threat to the environment and human health.

According to Alexander Golikov (Golikov, 2003) perception of biotechnology differs country to country as it shown below in Table 2.3. This perception can be adapted to GMO issue because if there is a product subject to debates, this is nothing than GMOs.

Table 2.3. Perception of Biotechnology: The National Flavor

US & Canada	Product is **safe** unless proven **unsafe**
UK	Product is **unsafe** unless proven **safe**
France	Product is **unsafe** even if proven **safe**
Austria	Product is **unsafe** especially if proven **safe**
India	Product is **safe** even if proven **unsafe**
Uganda	Product is **safe** especially if proven **unsafe**
Ethiopia	**Product is unsafe even if not developed yet**

Source: Golikov, Alexander (2003). *The Cartagena Protocol On Biosafety: Implications For National Regulation.* Presentation by Alexander Golikov from Center for Policy in GMO Risk Management, Moscow, Russia, on 17.12.2003 in Ankara.

Third issue in concern is the labelling issue which again reflects different regulative approaches. The U.S. stand was that GMO labeling was not necessary due to GMOs viewed as a molecular extension of classic plant breeding methods, so this does not constitute "material" information. Secondly, the principle is that GM food were not different than those developed traditionally. Therefore, given their substantial equivalence, GMOs would only require labeling if they contained allergens, or if they were substantially different, and therefore had different nutritional characteristics. But, the E.U's regulations put strict rules for labelling for all food includes GMOs because of safety issues.

b. GMOs Within the WTO Framework

Labelling , risk assessment and precautionary principle are also issues that are part of the WTO agenda with refer to the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement), the agreement on Technical Barriers to Trade (TBT Agreement) and the GATT. The GATT was established in 1947 with the central objective of limiting the ability of domestic vested interests to obtain protection against imports. It requires members not discriminate against foreign products in favor of like domestic products, requires members to not discriminate between like products from one trading partner in favor those from another which is refered as Most Favored Nation obligation. But discrimination to promote certain goals such as protection of human, animal or plant life or health is permitted under Article XX of the GATT, but only to the extent that discrimination is not arbitrary or unjustifiable. Primary focus was the reduction of tariffs and many tarif barriers to trade have been either eliminated or reduced to maximum levels; import quotas have also been reduced or eliminated. But as a result of domestic protectionist pressures instead of tariffs or quotas "non-tariff barriers to trade (NTBs)" occured. The reduction of tariffs also revealed a host of domestic regulations, such as health and safety regulations, labelling requirements, etc. that were not designed with a protectionist intent but which have the effect of inhibiting trade (Hobbs, Gaisford, Isaac, Kerr and Klein, 2002).

At the close of the Uruguay Round GATT negotiations, the WTO established to oversee multilateral trade negotiations between member nations on a permanent basis and also a number of ancillary agreements were signed (Hobbs, Gaisford, Isaac, Kerr and Klein, 2002). The two which are central to the case of GMOs are the SPS and TBT Agreements. As mentioned before the SPS Agreement established in response to a concern that regulations with a legimate domestic purpose of protecting human, animal or plant health safety could also be misused to protect domestic producer interests by restricting imports. The SPS Agreement recognizes that perceptions of safety are relative and may vary accross countries, so countries are allowed to specify their own acceptable levels of risk tolerance in their regulations but the risk tolerance levels allowed for imports must be the same as those applied to similar domestic products (Hobbs, Gaisford, Isaac, Kerr and Klein, 2002). National SPS measures must be based on a risk assessment and

scientific evidence and members must avoid applying their SPS measures in a way that creates "arbitrary and unjustifiable discrimination" and "disquised restrictions on international trade" (Stilwell, 1999).

TBT Agreement is not rooted in scientific principles and deals with technical measures such as packaging and labeling regulations or product standards rather than the safety of the product. The aim of the TBT Agreement is to ensure that WTO members do not use technical regulations and standards as implicit measures to protect domestic industries from foreign competition. A country can not impose labeling or packaging regulations against the imports from only one country.

c. The E.U. Moratorium on Genetically Modified Foods/Crops and the WTO Case

In 1990, the E.U. legislation on the regulatory approval pf GMOs was adopted under Directive 90/220 and between the years 1994 and 1998 the commercial release of 18 GMOs (9 crop products) was authorized in the E.U. through the regulatory approval system. In 1997 Austria, France, Germany, Italy, Greece and Luxemburg banned modified crops approved by the E.U. and by October 1998 authorization of applications stopped. Ministers from Denmark, France, Greece, Italy and Luxemburg issued a joint statement that they would suspend new authorizations pending EU adoption of GMO labelling and traceability regulations. The Austrian, Belgian, Finnish, German, Netherlands and Swedish delegations issued a statement emphasizing the need to "take a thoroughly precautionary approach" to new authorizations and these declerations formalized the *de facto* moratorium on GMO approvals.

On 13 May 2003, the U.S. and Canada requested consultations with the E.U. concerning certain measures taken by the E.U. and its Member States affecting imports of agricultural and food imports from the U.S. and Canada. According to the U.S., the measures at issue appear to be inconsistent with the E.U.'s obligations under:

a. Articles 2, 5, 7 and 8 and Annexes B and C of the SPS Agreement,
b. Articles I, III, X and XI of the GATT 1994
c. Article 2 and 5 of the TBT Agreement

To its complaint the U.S. appended a list of biotech product applications for commercialization that had been submitted to the E.U. Member States from April 1996 through July 2001, all of which either were pending approval or which had been withdrawn. Suppan mentioned the attitudes of the two parties as (Suppan, 2005)

> *"The EC characterized the filing of the complaint as "legally unwarranted, economically unfounded and politically unhelpful [with regard to EC efforts to develop a regulatory system for GMOs]." Two weeks later, President George Bush brought the trade dispute to wider public attention by charging that the allege moratorium on GMO approvals was hindering efforts to reduce hunger in Africa."*

On 7 August 2003, the U.S., Canada and Argentina each requested the establishment of a panel. This first request deffered by the Dispute Settlement Body (DSB) and further to second requests to establish a panel from the U.S., Canada and Argentina, the DSB established a single panel at its meeting on 29 August 2003.

In March 2004, the first submissions of evidence began. In addition the U.S., Canada and Argentina, Australia, Brazil, Chile, Columbia, India, Mexico, New Zeland and Peru requested consultations with the E.U. and reserved their rights as third parties to benefit from the ruling. The first U.S. submission to the dispute panel largely comprises a "statement of facts" followed by a legal discussion that focuses on the SPS Agreement. The structure of the U.S. legal argument is in three parts: "1) General Moratorium Violates the SPS Agreement; 2) Product-Specific Moratoria Violate the SPS Agreement: and 3) EC Member State Marketing or Import Bans Violate the SPS Agreement." The E.U. submits, "The SPS Agreement was not intended to address the prevention of risks to the environment" with refer to the Cartagena Protocol. Since the Convention on Biological Diversity, to which the protocol belongs, is not even allowed to be an international observer at the meetings of the WTO Trade and Environment Committee (which established to deal with the conflicts between environmental arrangements and the WTO), but the SPS agreement requires WTO members to base their SPS measures on international standards. According to complainants in order for a sanitary measure to be established there must be a "rational relationship between the measure and the risk assessment", in this case there would be no relationship whatsoever because no risk assessment has been undertaken. Therefore, it is clear, according to the Complainants position, that the EC moratoria violates Art. 5.1 of the SPS Agreement. Also the E.U. argues, "No evidence on the existence of a 'moratorium' on the approval of GMOs has been identified". According

to the E.U. argument, evidence of a moratorium would be an official E.U. communication declaring a moratorium, and no such communication was issued.

While the US only presented claims of SPS violations in its first submission to the Panel, Canada and Argentina also raised issues related to other WTO Agreements. Both countries consider that the E.U. challenged measures are inconsistent with the TBT Agreement and with the GATT. Furthermore, Argentina considers that the moratoria is violating E.U. WTO obligations to developing countries arising from the special and differential treatment clause, which is present in the SPS and in the TBT Agreement.

3. ANALYSIS OF THE COMPARABLE DATA OF THE U.S AND THE E.U MODEL

3.1. Methodology

As mentioned in the begining of the literature review section, both conceptual and statistical definitions and classification of biotechnology show the multidisciplinary structure of biotech. Consequently biotechnology policy deal with wide range of subjects and this makes it hard to decide and group the policy indicators. While adding and analysing all biotech related applications of countries that deals with biotechnology makes no difference of preparing a report on biotech policies, the aim of this study is to show the differences of two models and they should be comparable. There is different areas of interests in indicators across the U.S. and the E.U. For example in a working paper of OECD that examines comparable biotechnology statistics in selected countries one of the topics is publicly funded biotechnology research and development (R&D) statistics and the U.S. which invest quite heavily in biotechnology R&D is not included because the information is not publicly available (Devlin, 2003). Also, sectoral analysis and influences of them to countries' economies is restricted with GMOs due to the lack of information. The U.S. do not make a differentiation in industry sectors as biotechnology because of biotech's connection with wide range of sectors like agriculture, pharmaceuticals, food and etc. therefore market analyse is not mentioned in this study.

Data collected according to well defined guidelines, like books that individualy examines both subjects that in general concern and subjects that need expert knowledge or reports and articles that reflect different views on questions in dispute and sources of some institutions like patent offices that contains statistical datas. All of the headings under data processing section, except venture capital and dedicated biotechnology firms, are also

underlined in the literature review section which gives information about the subject in general.

The first section of data analysis composed of culture collection comparisons to figure real stage of biotechnological development of a country. Culture collections are crucial indicators because they are the main source of microbial resources which are the raw material of biotech industry.

Secondly, comparison of the U.S. and the E.U approach in IPR issues linked with biotechnology is analysed. The main issues in dispute are technology transfer, access to genetic resources, benefit sharing through appropriate technology transfer and access to genetic resources, bioprospecting, patentable subject matter and plant variety protection. Their attitude and decisions taken in a legislative manner is one indicator that shows the difference of two models. Also patent statistics that indicates IPR applications of countries are included to this section, too.

Thirdly GMOs are compared from the regulative approaches and trade statistics point of view. GMOs are one of the most matter in question and related debates make the most sharp distiction between the U.S. and the E.U. Beside different regulative measures in national manner also the debate moved to international arena by the moratorium of the E.U. to any GMO included imports which effected especially the U.S. originated ones. The case of GMOs is now delibrated in the WTO and it is indispensible topic of biotech policies.

Last analysed issue includes some comparable data which are not cited in the literature review section due to their link to countries competitiveness in biotech. Although competitiveness contains lots of factors like specific market analysis, only venture capital investments and comparison of dedicated biotechnology firms made because of the lack of publicly available data. Available ones generally only for the U.S. or for the E.U and as fragmentary datas are not appropriate for data integrity they are not included. These two indicators chosen because biotech business nature, firm structures, investment ratios show how policies shape real markets.

Unfortunately, information for the indicators mentioned above is very limited or not exist at all for Turkey. Therefore it is hard to figure a current situation for Turkey in these fields but insofar available information is tried to be mentioned.

After the analysis of derived information for indicators, every topic in the data analyse section followed by situation for Turkey. It is not included as seperate section to provide integrety in expression. Discussion of the subject which reflects opinions with refer to the results of comparisons and prediction of prospects for Turkey included in the conclusion part.

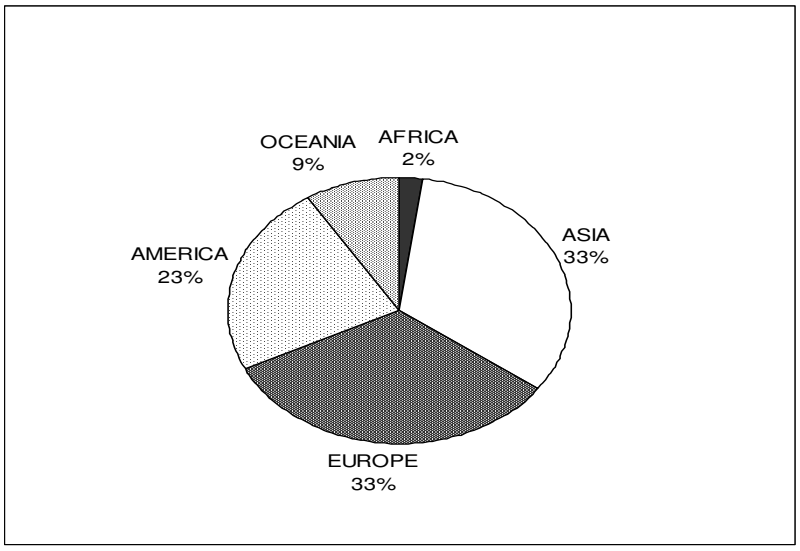
3.2. Culture Collections

The importance and value of biological resources cited under biological diversity conservation section in the literature review part. One way of conservation of them is by *ex-situ* conservatories like culture collections (CCs). They are an essential part of biotechnology infrastructure, providers and repositories of new samples that are used for scientific, industrial, agricultural, environmental and medical R&D and applications. Also their expertise in identification, characterization and preservation of biological resources is beneficial for industry.

When their importance from many sides is in consider, they are one of the main policy issue of countries in biotechnology field. Therefore, analysis made under this assumption would provide information about biotechnological development level of a country. Analysis include comparison of the number of CCs and comparison of the culture numbers.

3.2.1. Comparison of Culture Collection Numbers

Intercontinental distribution of culture collection numbers according to World Data Centre for Microorganisms' (WDCM) 2003 statistics show that Asia and Europe acquire the same percentage of CC numbers with %33 and America follows with %23, Ocenia with %9 and Africa with %2 (Figure 3.1). WDCM used as the source of data included here because it provides a comprehensive directory of culture collections, databases on microbes and cell lines, and the gateway to biodiversity, molecular biology and genome projects. It is now maintained at National Institute of Genetics (NIG), Japan and has records of nearly 476 CCs from 62 countries. The records contain data on the organisation, management, services and scientific interests of the collections. Each of these records is linked to a second record containing the list of species held. The WDCM database forms an important information resource for all microbiological activity and also acts as a focus for data activities among World Federation of Culture Collections (WFCC) members.

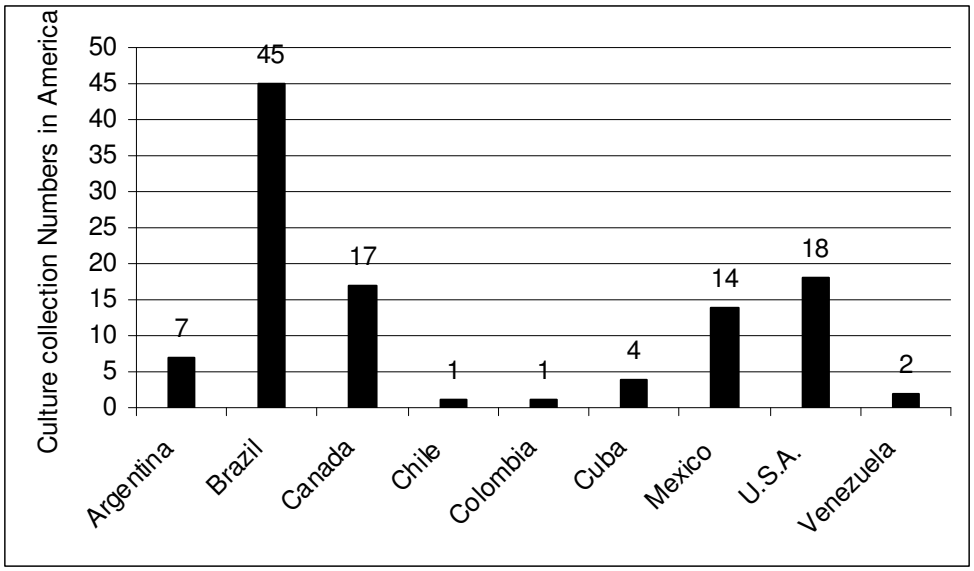


Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.1. Intercontinental Distribution of CCs

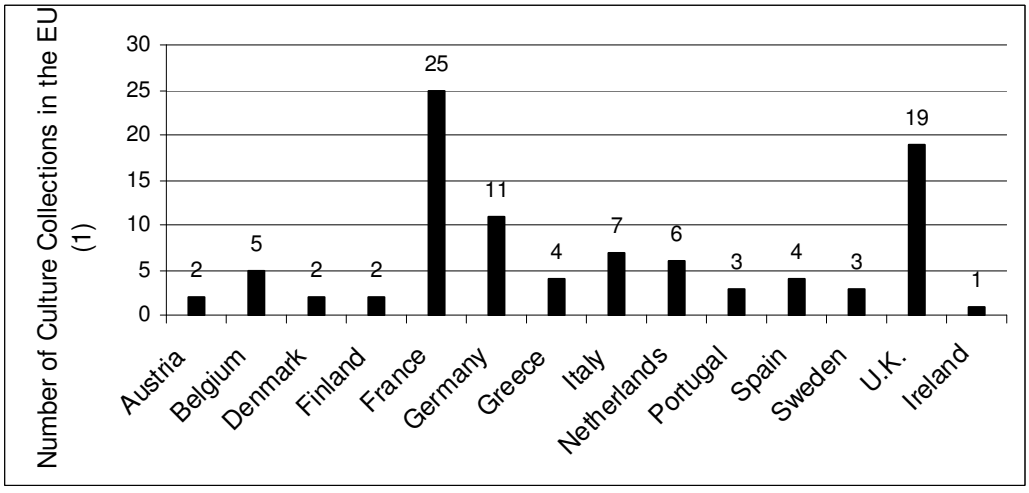
According to the same study of Gürsoy and Özer that based on WDCM statistics number of CCs in America and in Europe is as shown below[16]:

[16] See Annex 4 for distribution of CCs in other countries.



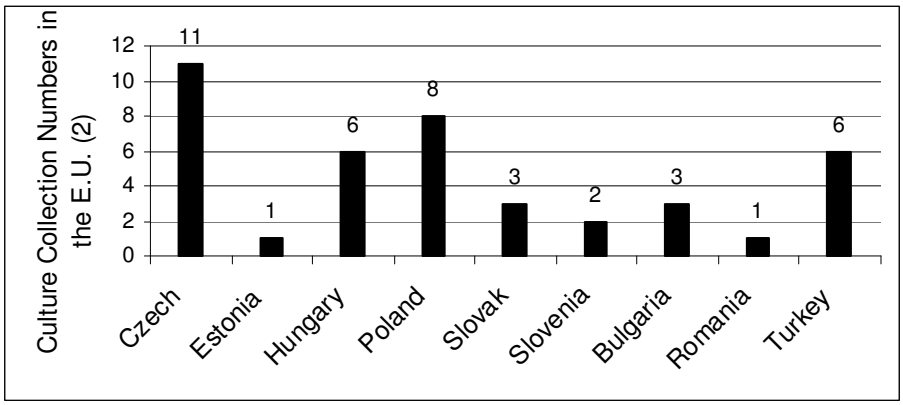
Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.2. Distribution of CCs in America



Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.3. Distribution of CCs in the EU Member Countries



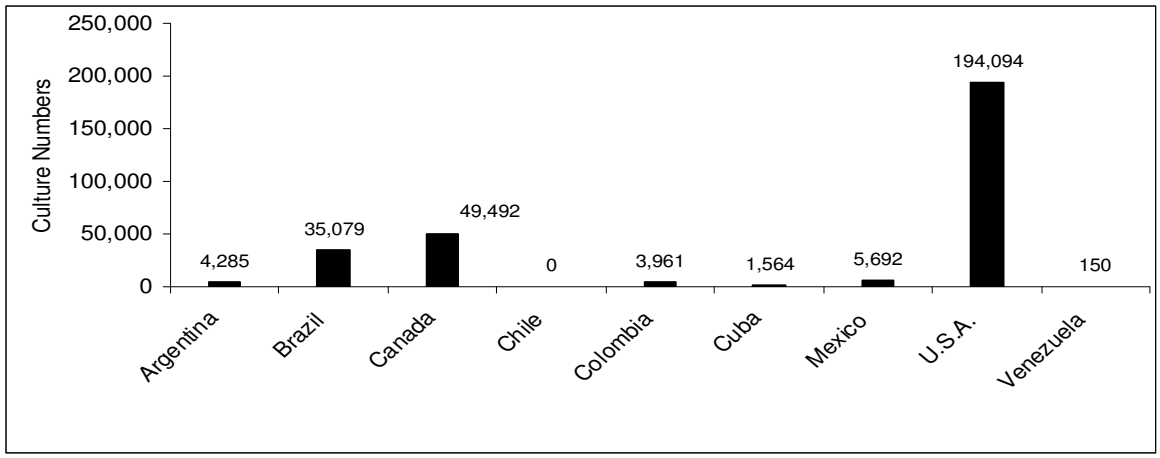
Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.4. Distribution of CCs in the New Member and Candidate Countries of the E.U

According to this data the U.S have more CCs than the most of the E.U. member states except France and the United Kingdom and the new member and candidate countries. But only the number of culture collections is not enough for comparisons. The number of cultures registered to these collections is also as important as the number of CCs.

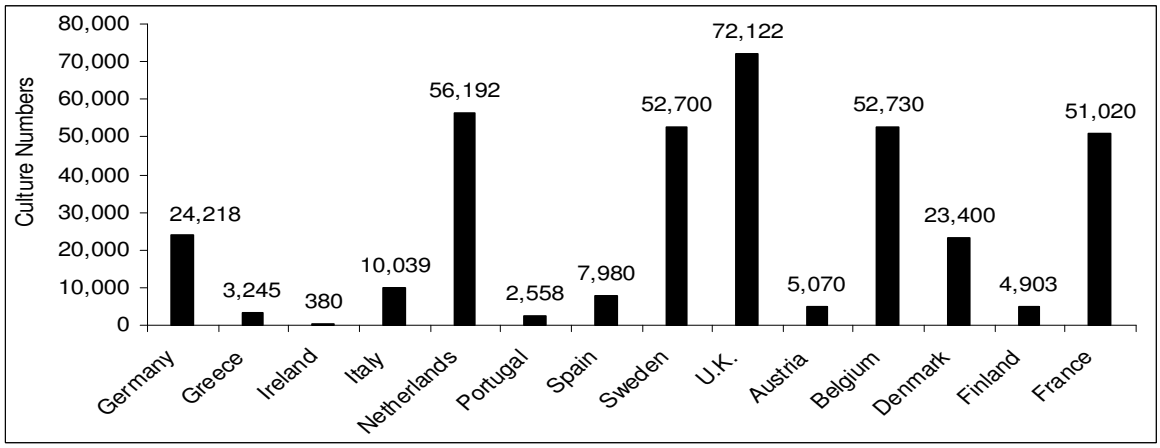
3.2.2. Comparison of the Culture Numbers Registered in CCs

Cultures that registered to collections are used in many scientific, industrial, agricultural, medical and environmental researches. This saves the time of researchers because without them, every user would have to "reinvent the wheel" and invest innurable hours in the costly recovery of organisms and genes and their characterization. Number of cultures in Europe and America is as shown in the figures below:



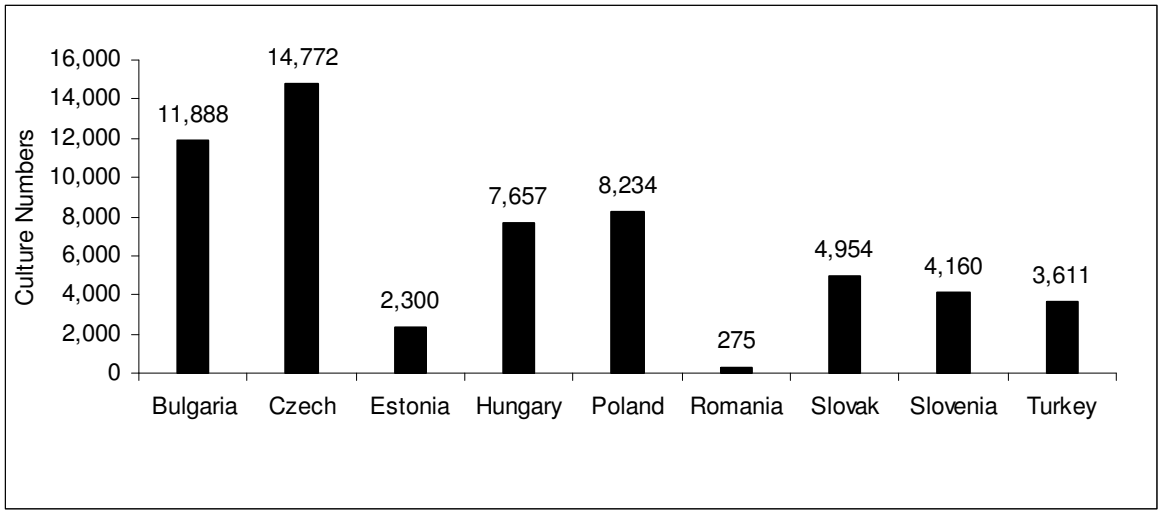
Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.5. Culture Numbers in America Hold by the Registered Collections



Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.6. Culture Numbers in the E.U. Member States Hold by the Registered Collections



Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

Figure 3.7. Culture Numbers in the New Member and Candidate Countries in the E.U. Hold by the Registered Collections

According to these data culture numbers in the U.S. is more than any country in the E.U. and also more than the candidate countries. Besides this the U.S. have the most culture numbers in the world according to the registered numbers to WDCM[17]. This shows that not only the number of CCs indicate the level of biotechnological development in a country, also the number of cultures preserved in these collections is one of the indicators.

3.2.3. Situation in Turkey

There are six CCs in Turkey which are; Ege-Microalgae Culture Collection, Culture Collection of Animal Cells, Centre for Research and Application of Culture Collection of Microorganisms, TUBITAK Marmara Research Centre Culture Collection, Muğla University Collection of Microorganisms and Refik Saydam National Type Culture Collection. Three of them are governmental and others are university based culture collections. Number of culture numbers is about 3.611 (Figure 3.7).

[17] See Annex 4 for registered culture numbers of countries.

When it is compared with the U.S. Turkey is at a very low level from both culture collection numbers and culture numbers. Turkey is one of the biodiversity rich countries of South with respect to Northern countries. Therefore number of cultures hold in culture collections should be respectively higher but because of lack of awareness of the value of biological sources numbers are well below than the potential. Also absence of appropriate policy strategies for collecting and defining these resources, establishing links between the industry for more effective culture collections which provide many services, is another explanation for insufficient posisition of Turkey.

3.3. Comparison of IPR Related Policy Concerns

3.3.1. The U.S. Approach Trough Technology Transfer, Access to Bioresources and Benefit Sharing

Indusrialised countries like the U.S., have interest in high levels of IPR protected products, technologies and services because they are the main exporters of these. It is not only the products, tehnologies or services, also rights themselves in the form of licences to use patented processes, techniques and designs, copyrights, trade marks and franchises (Dutfield, 2002). As Michael Ryan mentioned (Ryan, 1998);

> *"U.S. multinationalmanufacturing enterprises increasingly transfer intellectual property internationally through the industrial processes that they sell abroad. Exports, as measured by royalties and licensing fees, amounted to about USD 27 billion in 1995, while imports amounted to only USD 6.3 billion. At least USD 20 billion of the exports are transactions between U.S. firms and their foreign affiliates."*

This balance of payments surplus is far higher than for any other country. Thereby it can be said that not only the technological changes also impacts of international trade led up to TRIPs Agreement. This agreement required the effective lobbying activities in the U.S. of intereset groups like legal and policy enterpreneurs and corporations, firms, bussiness associations and individuals like lawyers, consultants, certain company heads (Dutfield, 2002). Also it is stated in the same study that these actors suggested the solution as "effectively to impose on the world their interpretation of fair competition in high-

technology and creative industrial sectors by means of the global standardization of national IPR regulations as far as possible equivalent to the standards existing in the United States". But why the U.S. government was tended to identify the interests of these groups with the national interest. According to Dutfield the U.S.' concern in increasing competition in various high-technology sectors from other countries arised such a tendency.

> *"The reason why the U.S. government was predisposed to identifying the interests of these groups with the national interest is closely linked to a feeling of declinism experienced by the political elites during the 1980s. In large part this was due to increasing competition in various high-technology sectors from other countries, especially Japan, that the United States had hitherto dominated, and manufacturing generally from low-wage newly industrialising economies (NIEs) like South Korea, Taiwan and (though not strictly a NIE) China. This was generally felt to be largely due to blatant and widespread intellectual property piracy by these countries, which did not play fair when it came to trade, investment or industrial policies (including intellectual property and technology licensing regulation). The U.S. was very concerned about these countries having strategic trade and industry policies that protected domestic markets for local firms while benefiting considerably from exporting their goods to the United States and enjoying sizeable trade surpluses."*

According to Bhagwati, those governments (especially the U.S.) and the firms supporting TRIPs, implicitly held rights based argument such as "we invent the stuff, so it is ours and anybody who does not agree to our terms and conditions for using it is engaging in piracy and theft" (Bhagwati, 1998).

Up to these interpretations there is only the evident that when international trade and competition are in consider the U.S. is a strong defender of the IPR and pioneered TRIPs Agreement as a consequent. What makes think of the U.S. has a different approach in biotechnology policy related with IPR issues is, the U.S. has not been ratified the CBD yet. As a result of Earth Summit in Rio de Janerio in June 1992, where it was signed by 153 nations and the European Community (E.C.), the U.S. was the only nation attending the Rio Conference that did not sign the Convention. Michael D. Coughlin mentioned in his study about the CBD's problemeatic issues such as technology transfer, that "the Bush Administration cited dissatisfaction over the vague and ambiguous wording of some of the treaty's major provisions, wording which it felt left the U.S. biotechnology industry without adequate intellectual property protection and the government without control over its financial contributions to the cause of conservation". It should be noted that the Clinton Administration authorized its United Nations Ambassador, Madeleine Albright, to sign the treaty, because it wanted to ensure that the U.S. would be able to participate in negotiations

among the Parties to the Convention but the U.S. not ratified the CBD yet. In other words this caused because of the believes of the Administration under pressure of the US biotechnology lobby that such a treaty would weaken the position of the U.S. with respect to IPR protection under GATT, and hurt the competitiveness of its own biotechnology industry by allowing firms indeveloping countries to copy U.S. inventions and market them at cut-rate prices (Coughlin, 1993)

The strategy of the U.S. is different than other countries that ratified the CBD and there are some cases as to be the evident of this approach. First one is the agreement between the U.S. pharmaceutical firm, Merck and the government of Costa Rica, in late 1991.

3.1. Case Study: Merck-INBio Agreement with Respect to Technology Transfer Policy of the U.S.

Under the terms of the agreement, the National Biodiversity Institute (INBio), a non-profit scientific organization created by the government of Costa Rica, will provide 10,000 samples of plants, animals, and soil to Merck. Merck will have the exclusive rights to study these samples for two years, and will retain the patents to any drugs developed using the samples. In return, Merck will pay INBio $1 million up front, and will give the institute an additional $130,000 worth of laboratory equipment. Perhaps the most interesting part of the deal, at least from Costa Rica's perspective, is Merck's promise to pay royalties to INBio for any drugs developed from the biological samples provided. These royalties would be paid on all sales and not just sales in the United States or Costa Rica. As part of the deal, half of these royalties will go to the Costa Rican government's Ministry of Natural Resources, which Costa Rica says will use all of those proceeds for the conservation of biological diversity. INBio refuses to disclose the precise percentage amount of the royalties, but its director Rodrigo Gomez has stated, by way of illustration, that "if we had something like 2 or 3 percent of the shares of 10 good products coming out of Costa Rica, Costa Rica would be receiving more external resources than what we are currently receiving from bananas and coffee put together." Although ten good products out of 10,000 samples is unlikely, and the time required to develop even a promising discovery can be ten years or more, the payoff can be great. One example, in terms of dollars, of the kind of revenue that even one such discovery can generate is the anti-parasitic veterinary drug Ivermectin. First discovered in a soil micro-organism from Japan, it brought Merck more than $100 million in sales in 1991.

Source: Coughlin Jr, Micheal D. (1993). *Using the Merck-INBio Agreement to Clarify the Convention on Biological Diversity.* Columbia Journal of Transnational Law 31 (2):337-375

What achieved by this agreement in terms of technology transfer and the protection of IPR is, Costa Rica will avoid the injustice of paying royalties on products which orginated in its own territory and recieve royalties on sales of those products and Merck will be the exclusive owner of the patents on any drugs derived from the use of these samples. “While Costa Rica did not receive technology that would enable it directly to copy Merck’s drugs, it did receive laboratory equipment, the ultimate value of which could

well exceed several times its market value of the USD 130.000" (Coughlin, 1993). Receiving such equipment could turn out as an advantage for the Costa Rican biotechnology industry in the future although Merck retains the patents.

Other examples shows that what is indispensable for the biotech industry of the U.S. is appropriate protection of the technology and the inventions. Agreements of Genentech, Hoffmann-La Roche, and Amgen that are all U.S. originated firms, show that if the technology is properly protected, collaboration and transfer overseas need not result in the loss of a leadership position to the country pioneering the innovation (Rathmann, 1999). As Rathmann (1999) mentioned, in the case of Genentech, it transferred human growth hormone technology to KABI in Sweden to receive royalties on sales outside the U.S. and Hoffmann-La Roche was granted the worldwide licence for ά-interferon and developed a relationship with Takeda in Japan which eventually resulted in technology transfer to Japan. Also Amgen formed a relationship with Kirin Brewery Ltd. in Japan that involved complete technology transfer and this agreement assured that Amgen would have exclusive rights to the patents and the technology in the U.S.

Cases with respect to the U.S. approach in terms of technology transfer (biotechnology), access to genetic resources, benefit sharing and as the U.S still not ratified the CBD shows that protection of inventions and related technology with IPR is indispensable for the U.S and the U.S. chooses bilateral agreements as a result. On the other hand, the E.U. is one of the membes both to TRIPs and the CBD which conflicts with each other in many ways as mentioned in the literature review section. Debates on the appropriate benefit sharing through technology transfer and access to genetic resources makes the approach of the E.U. uncertain and there is no functional solution for industry's needs. In the absence of invention and technology protection with IPR, biotechnology investors would lose their one important motives because biotech requires high risk investment. Therefore, commercialization of biotech products would not be achieved effectively even though technological capacity is well developed without market entry with appropriate technology protection.

In the case of Turkey, it is one of the biodiversity rich countries with immature technological development and infant industries. It is not the absence of capacity for

biotechnology that induce lack of industrial initiatives because Turkey has both trained staff, resources for research and financial support for R&D. But what is lacking is linkages between investors and scientific environment or industry and academia. Because of the awareness of the value of resources and technology protection, investors could find it too risky to initiate a new form of industrial production in a new area like biotech.

3.3.2. The E.U. and the U.S National Legislation Comparison with Respect to Patentable Subject Matter Issue

The study of Demaine and Fellmeth (2002) mentions national patent law of the U.S. in the field of biotechnology and gives examples of cases that show the U.S applications with respect to patentable subject matter issues. As stated in this study in July 2000, Todd Dickinson, the Director of the US PTO, declared to the Subcommittee on Courts and Intellectual Property of the House Judiciary Committe:

> *"there are so many chemicals in the human body that, if we ruled them all off limits to patenting, we would rule out an extraordinary number of valuable and important inventions…Without the funding and incentives that are provided by the patent system, research into the basis of genetic diseas and the development of tools for the diagnosis and treatment of such diseases would be significantly curtailed."*

Up to 1952 which the Patent Act entered into force, main interpretations made under "purification doctrine". In the 19th century mere purification of subject matter was not enough for patentibility. American Wood Paper Co. (plaintiff) v. Fibre Disintegrating Co. (1874) case is one important example of the doctrine that mere purification of a preexisting substance does not create a new, patentable product without a significant alteration to the preexisting product (Demaine and Fellmeth, 2002).

After 1952 Patent Act the patentable subject matter requirements set forth in sections 101, 102, and 103 and each section sets some substantive preconditions for patentability.

According to section 101, the claimed subject matter must have been "invented or discovered" by the applicant, it must be "new", it must be "useful" and it must be a process

or a product. The requirement of newness interpreted by courts generally as exluding from subject matter certain discoveries that lack invention, such as laws of nature and naturally occuring products and processes. The term utility interpreted by US PTO as, the applicant must show a specific, substantial and credible use for the claimed invention (Demaine and Fellmeth, 2002).

According to Section 102, to be patentable, aproduct or process must be "novel". Novelty defined as the claimed product or process was not previously known or used by any other person in the U.S. The "nonobviousness" criterion, defined in Section 103 and this means that the product or process not be self evident to a person having ordinary skill in the relevant arts (Demaine and Fellmeth, 2002).

The foundational case for the patenting of living organisms in the U.S. is the much debated Diomand v. Chakrabarty (1980). By 1952 Patent Act the U.S patent law became much more flexible in relation to obtaining patents in the biological sciences. Until Chakrabarty case the US PTO rejected claims to microorganisms as not falling within Section 101 and because of the naturally occuring phenomenon. The U.S. Supreme Court held that the original living cell had been radically altered by human intervention and was not a product of nature and therefore not subject to rejection on that ground (Gaythwaite, 1999). Begining in 1987, the US PTO Board of Patent Appeals and Interferences and the new U.S. Court of Appeals for the Federal Circuit began shaping the patent law in a manner that allowed patents on naturally occuring phenomena as long as the applicant included the phrase isolated and purified in the specifications (Demaine and Fellmeth, 2002).

In the case of the E.U. the European Patent Convention (EPC) which came into force in October 1977 and Directive 98/44/EC which entered into force in July 1998 set provisions about patentable subject matter. Articles 52 and 53 of the EPC includes provisions for patentable inventions and exceptions to patentability and it does not forbid the patenting of living things themeselves. It also expressly requires an inventive step ad excludes mere discoveries from patentable subject matter. Directive on the Legal Protection of Biotechnological Inventions (98/44/EC) sets out which inventions involving plants, animals or the human body may or may not be patented. It requires the Member

States to allow the patenting under certain conditions of inventions which may have an industrial application. It contains a number of definitions and rules on interpretation what can and cannot be patented, and to resolve demarcation problems that arise with the patenting of new plant varieties. The directive contains provisions intended to harmonise the issuing of patents by different offices and to lead to uniform legislation. It also defines the scope of the protection provided by a patent on a biotechnological invention. Opponents to the directive say that living things are not inventions and therefore cannot be patented. Many scientific and non-governmental organisations demand a suspension of the directive. The Commision is currently pursuing infiringement proceedings against nine Member States (Germany, Austria, Belgium, France, Italy, Luxembourg, the Netherlands, Portugal and Sweden) for their failure to transpose the Directive into national law by the 30 July 2000 deadline. To date only four Member States have not implemented the Directive: Italy, Luxembourg, Latvia and Lithuania.

Directive 98/44/EC, Paragraph 16 states explicitly that "the simple discovery of one of the elements of the human body or one of its products, including the sequence or partial sequence of a human gene, can not be patented". It seems that naturally occuring phenomena would cause discussions among the E.U Member States due to the intranational structure of the Union and repressive attitude of some Member States and there is a long way for the Member States to adopt standards as adopted in the U.S.

From the side of plant variety protection as discussed in the report of GRAIN (an international non-governmental organisation which promotes sustainable management and use of agricultural biodiversity) For a Full Review of TRIPs 27.3(b) (2000):

> *"The US wanted full patent protection for all fields of technology but the Europeans prohibit patents on plant and animal varieties, and essentially biological processes for the production of plants and animals, under the European Patent Convention. A compromise was reached: TRIPS would use the language of European law as a starting point."*

3.3.3. Patent Statistics

Advantage of using patent datas to track innovative activities is due to nature of patenting process. They reflect the capacity of a firm in particular and accumulated

numbers reflect the capacity of a country to generate change and improvement over an existing body of knowledge in a particular area technology. Also there are major differences amongs countries in procedures and criteria for granting patents as discussed above. For these reasons, patent statistics chosen as a very important indicator, so by this way the regulative responses can be compared in the basis of their functionality. If regulations are supportive enough for innovative activities then their functionality from this vies can be measured by patent statistics.

Data on patent statistics can be characterized in two path. The first one is the patent data which are collected based on US Patent Class (UPSC) system[18]. Second one is number of patents granted by priority date to USPTO and EPO according to the International Patent Classification (IPC) codes[19].When the former is in consider the U.S. patent statistics are as shown in Table 3.2:

USPC Preliminary Class	Number of patents 1991-2000
Animal	297
Plant	2290
Microorganism	2403
Biological Materials for therapeutic application	8852
Biological Materials with generic applications	7062
Tissue culture	2249
Genetic engineering	6074
Biosynthesis	3363
Biosensors	10900
Methods of analysis (non-biological)	410
Apparatus	2180
Bio-separation and cleaning	1261
Fertilizers & Pesticides	186
Bioinformatics	116

Source: Patel,Peri (2003). UK Performance in Biotechnology-related Innovation: An Analysis of Patent data. SPRU, Final Report Prepared for the Assessment Unit of the UK Department of Trade and Industry,University of Sussex

Table 3.2. US Patenting by USPC Biotechnology Classes Between 1991-2000

[18] See Annex 5 for USPC classes associated with each biotechnology field.
[19] See Annex 6 for IPC codes associated with each biotechnology field.

Unfortunately, same data for other countries is not available but trends in patent shares of U.S. patenting by country of origin of inventor can be helpful for prediction. Table 3.3 shows the trends in patent shares of U.S. patenting by country of origin of inventor and includes five leading economies (UK, Germany, France, Italy, Sweden) of the E.U. other than the U.S. The numbers indicate that U.S. investors accounting for around two thirds of all patenting in the latest period as measured by its share of all U.S. patenting in the different fields of biotech.

Another comparison with the given countries mentioned in Table 3.3. can be made under patent citation analysis. Patent citation analysis include how frequently patents granted to investors from a particular country. The basic assumption is that the frequency of citation is a reasonably good Proxy for both the technological and economic value of a patent. Table 3.4 shows that patents granted to US investors are amongst the most highly cited, both at the accumulated level and within each of the ten technical fields.

Table 3.3. Trends in Patent Shares of US Patenting By Country of Origin of Inventor:1986-2000

	All Biotechnology	Plant	Microorganism	Biological	Biological Materials for therapeutic applications	Biological Materials with generic applications	Tissue culture	Genetic engineering	Biosynthesis	Biosensors	Apparatus	Bioseparation and cleaning
UK	1986-90	3,8	3,7	3,3	4,2	2,8	2,6	2,2	4,9	3,9	4,2	3,0
	1991-95	2,7	4,4	2,3	3,2	2,1	1,3	2,7	3,4	2,7	2,9	1,8
	1996-00	3,5	2,6	3,9	4,3	2,8	1,8	3,2	3,8	3,7	3,1	4,0
Germany	1986-90	6,4		2,9	5,7	6,3	5,6	4,7	7,8	7,5	6,5	12,1
	1991-95	5,1	1,7	3,5	5,1	5,6	2,1	3,7	6,9	6,1	4,8	6,1
	1996-00	3,9	3,1	2,5	3,7	3,8	2,7	3,6	5,4	3,9	7,1	6,0
France	1986-90	3,0	2,9	3,1	4,3	3,1	0,9	2,0	3,1	2,1	3,8	1,7
	1991-95	2,9	2,0	2,3	3,5	3,5	2,1	1,8	3,5	2,5	3,2	3,3
	1996-00	2,9	1,7	4,0	3,2	2,4	2,2	3,0	4,1	2,9	2,7	1,9
Switzerland	1986-90	1,3	1,5	1,0	2,1	0,6	3,5	0,5	1,7	1,0	1,5	1,3
	1991-95	1,4	0,3	1,9	1,8	0,8	1,0	1,7	2,9	0,5	2,0	2,9
	1996-00	1,0	0,5	1,5	1,0	1,4	0,5	0,8	1,3	0,6	2,6	0,8
Italy	1986-90	1,4		0,7	2,5	1,9	0,4	1,0	1,1	0,7	0,8	3,0
	1991-95	1,3		1,3	2,2	1,6	1,0	0,9	1,6	0,7	0,7	1,4
	1996-00	0,8	0,2	1,3	1,3	0,9	0,5	0,7	1,6	0,4	1,2	0,5
Sweden	1986-90	0,9	1,5	0,7	0,8	1,1	0,4		0,5	1,4	1,1	0,9
	1991-95	0,8		1,0	0,9	1,2	0,7	0,4	0,4	0,8	1,0	0,8
	1996-00	0,9	0,1	0,6	1,5	0,9	0,4	0,6	0,9	0,9	1,8	0,4
Japan	1986-90	14,6	5,9	16,9	11,7	16,7	10,8	12,0	26,3	11,0	13,8	13,4
	1991-95	13,9	7,6	12,3	11,5	17,9	8,2	11,2	28,0	10,6	9,9	12,4
	1996-00	7,8	3,2	8,8	6,3	10,2	5,1	6,2	21,1	6,4	8,0	11,6
Canada	1986-90	23,1	5,1	1,9	2,5	1,8	2,2	1,5	2,4	1,4	4,2	2,2
	1991-95	2,3	4,7	2,6	3,0	2,4	1,8	1,9	1,1	2,1	2,4	2,5
	1996-00	3,0	2,8	3,1	3,8	2,5	2,6	3,5	1,5	2,8	1,7	3,7
USA	1986-90	60,1	67,6	62,1	58,7	59,6	68,8	70,6	44,1	66,5	58,6	50,9
	1991-95	62,5	72,6	63,8	59,9	57,5	75,8	68,9	45,2	68,8	66,2	61,2
	1996-00	67,6	77,1	64,9	64,2	65,6	78,5	71,1	48,8	71,8	62,3	57,7

Source: Patel,Peri (2003). UK Performance in Biotechnology-related Innovation: An Analysis of Patent data. SPRU, Final Report Prepared for the Assessment Unit of the UK Department of Trade and Industry,University of Sussex

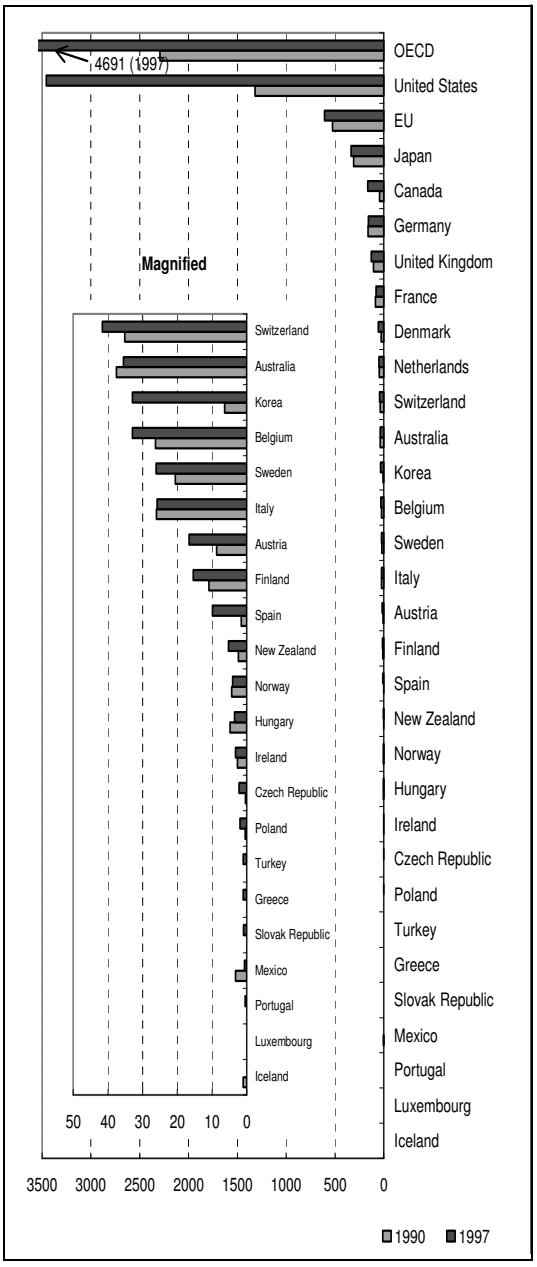
Table 3.4. Trends in the Patent Citation Index: 1986-2000

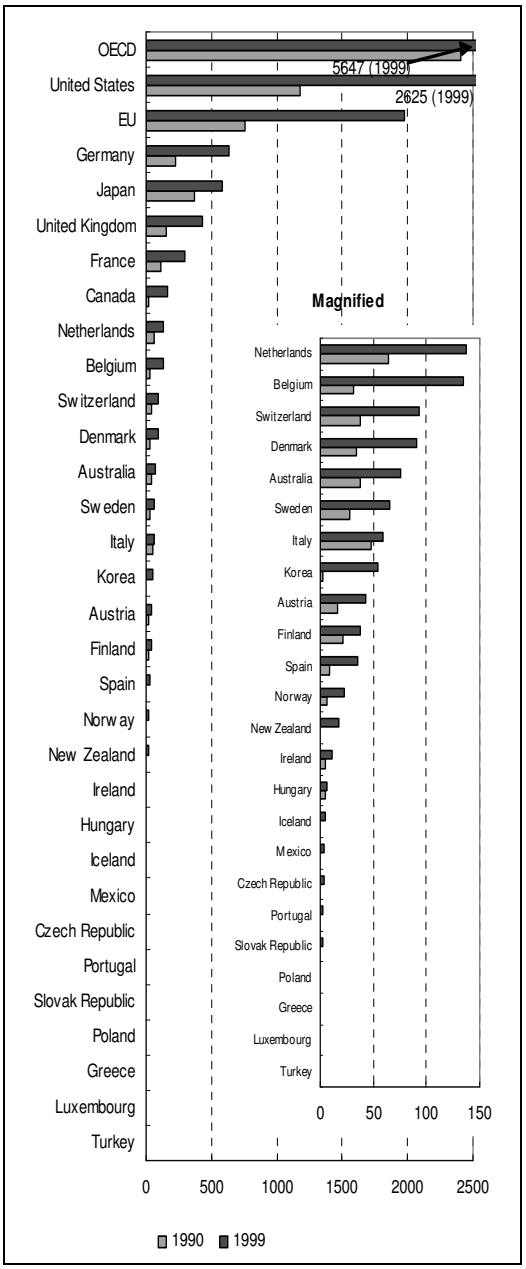
		All Biotechnology	Plant	Microorganism	Biological Materials for therapeutic applications	Biological Materials with generic applications	Tissue culture	Genetic engineering	Biosynthesis	Biosensors	Apparatus	Bio-separation and cleaning
UK	1986-90	0.88	0.13	0.63	0.86	0.86	0.50	1.57	0.73	1.10	1.00	0.62
	1991-95	0.86	0.85	1.07	0.67	0.95	0.67	0.82	0.63	1.09	0.95	0.49
	1996-00	0.89	1.14	1.08	0.68	0.85	0.34	0.49	0.94	1.15	1.06	0.79
Germany	1986-90	0.68		0.59	0.66	0.65	0.62	0.44	0.63	0.53	1.35	0.75
	1991-95	0.68	1.04	0.78	0.69	0.55	0.57	0.86	0.75	0.53	1.08	0.91
	1996-00	0.58	1.01	0.38	0.69	0.69	1.20	0.52	0.44	0.51	0.27	0.73
France	1986-90	0.63	0.27	0.62	0.60	0.64	1.30	0.70	0.42	0.80	0.54	1.30
	1991-95	0.61	0.43	0.75	0.57	0.59	0.89	0.96	0.70	0.58	0.52	0.68
	1996-00	0.53	1.03	0.30	0.52	1.19	0.38	0.61	0.51	0.37	0.50	0.21
Switzerland	1986-90	0.96	0.07	1.28	0.74	0.61	2.08	0.66	0.69	1.16	0.77	0.64
	1991-95	1.23	1.16	0.60	1.97	0.91	0.67	0.35	0.75	0.39	2.88	0.72
	1996-00	2.11	1.04	0.55	1.69	0.87	0.21	0.78	0.71	1.19	3.93	1.73
Italy	1986-90	0.36		0.00	0.34	0.52	0.27	0.37	0.48	0.33	0.26	0.44
	1991-95	0.41		0.42	0.59	0.53	0.28	0.11	0.33	0.44	0.33	0.14
	1996-00	0.52	0.00	0.52	0.88	0.60	0.21	0.56	0.89	0.15	0.10	1.11
Sweden	1986-90	0.82	0.07	0.85	1.09	1.01	2.39		1.68	0.54	0.65	1.27
	1991-95	0.82		0.86	1.00	1.07	0.25	0.59	2.25	0.50	0.77	0.58
	1996-00	1.27	0.00	1.47	1.76	0.85	1.42	0.20	0.95	1.81	0.38	0.00
Japan	1986-90	0.56	0.31	0.62	0.88	0.54	0.42	0.36	0.63	0.54	0.59	0.65
	1991-95	0.51	0.34	0.48	0.63	0.59	0.41	0.36	0.53	0.54	0.64	0.59
	1996-00	0.54	0.59	0.55	0.62	0.66	0.72	0.53	0.54	0.43	0.49	0.48
Canada	1986-90	1.19	2.67	1.10	1.18	1.54	2.63	0.75	0.66	0.96	0.64	0.87
	1991-95	1.09	1.06	0.59	0.95	1.59	0.60	1.32	3.17	0.68	0.96	1.23
	1996-00	0.80	0.35	0.53	1.07	1.09	0.85	0.77	0.62	0.73	0.27	1.11
USA	1986-90	1.21	1.16	1.12	1.17	1.22	1.06	1.19	1.42	1.15	1.18	1.20
	1991-95	1.19	1.09	1.23	1.18	1.21	1.13	1.18	1.35	1.16	1.05	1.15
	1996-00	1.12	1.02	1.22	1.08	1.10	1.09	1.17	1.44	1.12	1.03	1.25

Source: Patel,Peri (2003). UK Performance in Biotechnology-related Innovation: An Analysis of Patent data. SPRU, Final Report Prepared for the Assessment Unit of the UK Department of Trade and Industry,University of Sussex

Another kind of patent statistic classification is the data based on the number of patents granted to USPTO and EPO for priority years. According to Figure 3.8 the six leading countries for biotechnology patent applications and patent grants according to the EPO and the USPTO respectively are six of the seven largest world economies and the U.S. is the leading country in both of them. In the EPO and USPTO databases, country refers to the country of residence of the inventor. For patents with several inventors from different countries, the OECD applies "fractional counting", meaning that the patent is shared between the concerned countries to avoid double counting. Patents can be compared using different date measures. The priority date corresponds to the first filing worldwide and therefore closest to the invention date: to measure inventive activity a patent should be counted according to the priority date (Devlin, 2003). In Figure 3.9 for USPTO biotechnology patents granted between 1990 and 1997, shares have decreased markedly for the EU and Japan while increasing for the U.S (Devlin 2003).

As a result the U.S. have a significant leadership when patents are in consider. As mentioned before the U.S. is one of the main technology exporter, thus like in the culture collection and culture number examples, patenting one of the areas that the U.S. protect its dominance to its competitors.

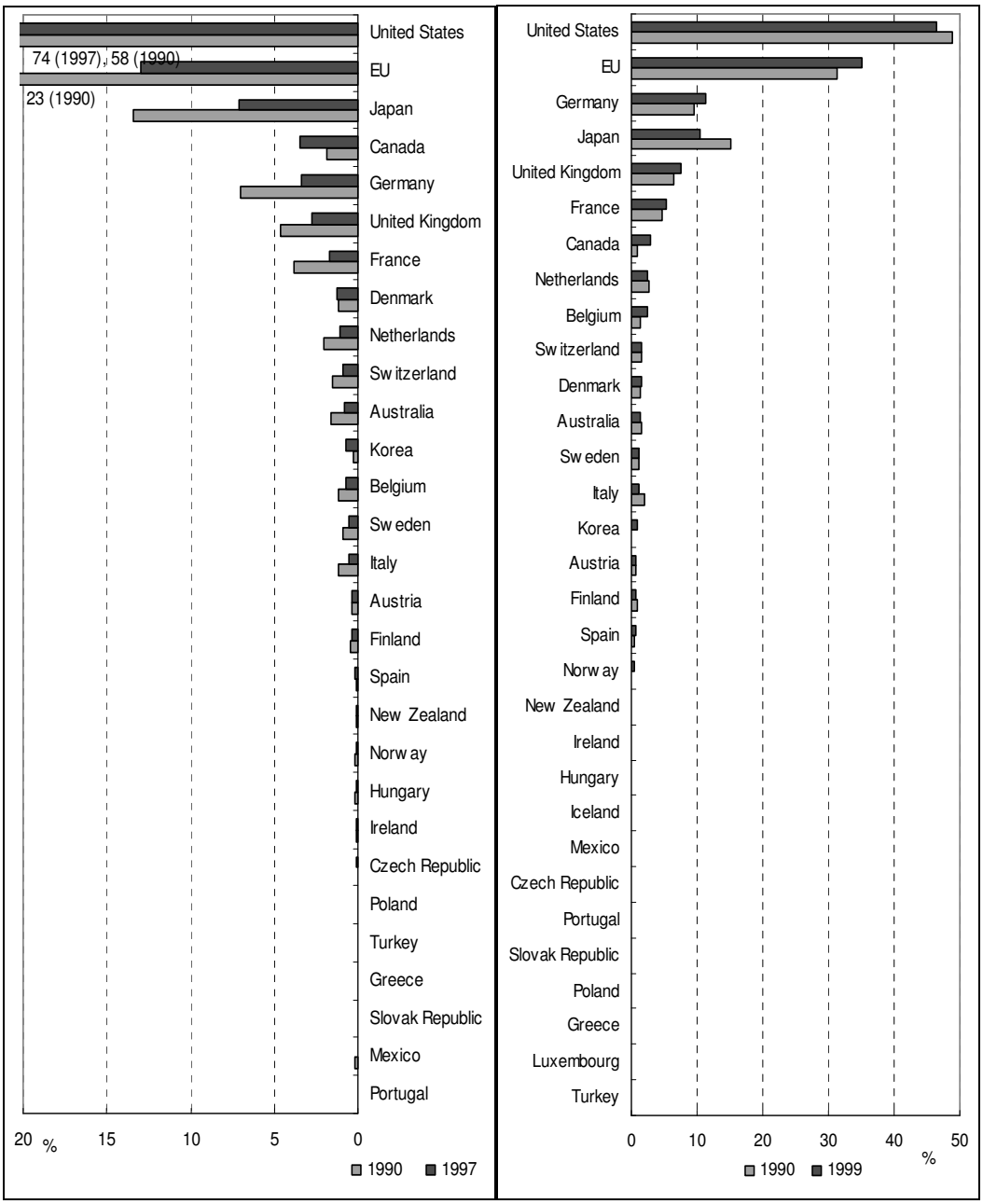




Source: Devlin, Andrew (2003). An Overview of Biotechnology Statistics In Selected Countries. Paris: OECD DSTI/DOC (2003) 13

Figure 3.8. Share of USPTO biotechnology patents granted for priority years 1990 and 1997

EPO biotechnology patent applications for priority years 1990 and 1999



Source: Devlin, Andrew (2003). An Overview of Biotechnology Statistics In Selected Countries. Paris: OECD DSTI/DOC (2003) 13

Figure 3.9. Share of USPTO biotechnology patents granted for priority years 1990 and 1997

Share of EPO biotechnology patents as a share of total OECD biotechnology patents, 1990 and 1999

3.3.4. Situation in Turkey

The United States, the European Union and Turkey have been in negotiations over the improvement of Turkey's intellectual property regime for several years. With the conclusion of the Customs Union Decision between Turkey and the E.U., Turkey has now committed to having a TRIPs-consistent patent law in place. The patent law issued by Executive decree in June 1995, however, falls well short of TRIPs standards like conditions of patentability. Turkey's IPR procedures are far from the discussions made under the U.S. and the E.U. IPR comparisons. Turkey's patent law is entered into force in 1995 and therefore it can not be compared with nor the U.S. patent procedure neither the E.U.'s.

Turkey is a Party of the CBD and also a member of the WTO. As discussed before the two agreement have conflicts or at least it is claimed like that by many arguments. But beside the absence of effective legislations for innovations or protection of the rights of inventors (which is the main motive of investment), also there is no literally discussion on these subjects.

One consequent of absence of appropriate protection in Turkey for biotechnological advancements, there is no patent statistics. This is the evident of Turkey's lack of capacity to generate change and improvement over an existing body of knowledge in biotechnology.

3.4. Comparison of GMO Related Issues

3.4.1. Trade of Genetically Engineered Crops

Crop varieties developed by genetic engineering were first introduced for commercial production in 1996 and the area covered by genetically engineered crops has increased over the past seven years, reaching 58.7 million hectares in 2002 and in 2004 it is estimated as 81.0 million hectares. The United States, with 39 million hectares of genetically engineered crops, represents 66% of the global total of genetically engineered crops by area. Argentina and the United States account for 89% of all genetically engineered crops (Table 3.5). The area covered by genetically engineered crops is expected to continue its increase. The increase in biotech crop area between 2003 and 2004, of 13.3 million hectares or 32.9 million acres, is the second highest on record. In 2004, there were fourteen biotech mega-countries (compared with ten in 2003, Paraguay, Spain, Mexico and the Philippines joining the mega- country group for the first time in 2004), growing 50,000 hectares or more, 9 developing countries and 5 industrial countries; they were, in order of hectarage, USA, Argentina, Canada, Brazil, China, Paraguay, India, South Africa, Uruguay, Australia, Romania, Mexico, Spain and the Philippines. During the period 1996-2004, the accumulated global biotech crop area was 385 million hectares, equivalent to 40% of the total land area of the USA or China, or 15 times the total land area of the UK (James, 2004). The continuing rapid adoption of biotech crops reflects the substantial improvements in productivity, the environment, economics, health and social benefits realized by both large and small farmers, consumers and society in both industrial and developing countries.

Biotech crops were grown by approximately 8.25 million farmers in 17 countries in 2004, up from 7 million farmers in 18 countries in 2003. Notably, 90% of the beneficiary farmers were resource-poor farmers from developing countries, whose increased incomes from biotech crops contributed to the alleviation of poverty (James, 2004).The main genetically engineered crops are soybeans, corn, cotton and canola. Genetically

engineered soybean crops account for close to half of all world soybean crops.(James, 2002)

Table 3.5. Genetically engineered crops (millions of hectares), 2004

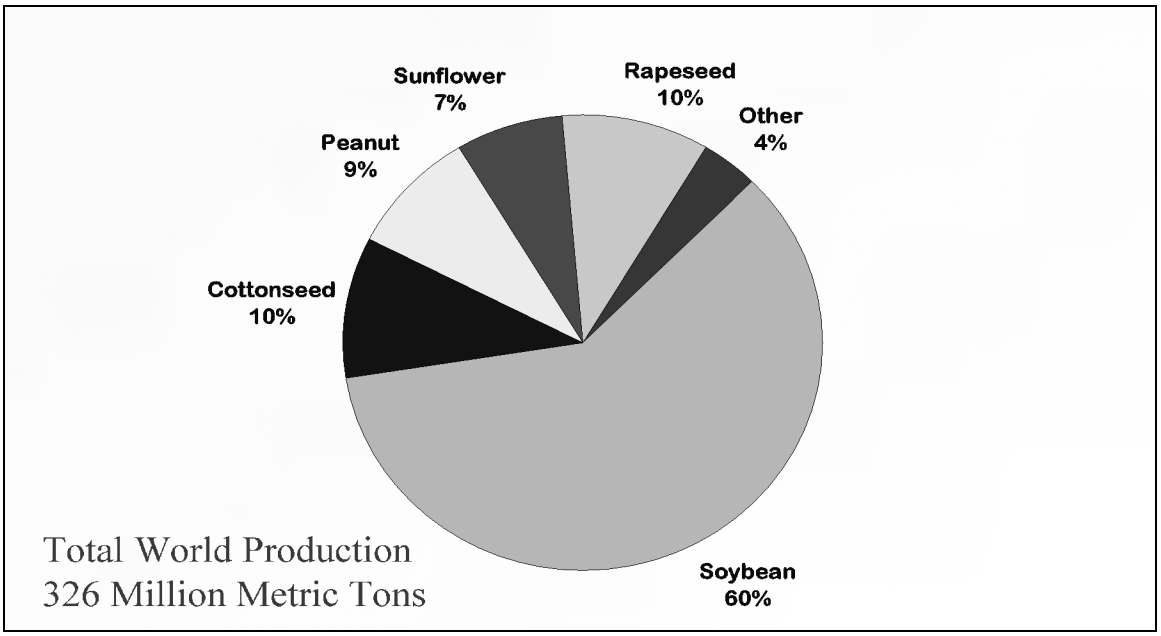
	1996	1997	1998	1999	2000	2001	2002	2004
Argentina	0.1	1.4	4.3	6.7	10	11.8	13.5	16.2
Australia	<0.03	0.05	0.1	0.1	0.15	0.2	n.a	0.2
Canada	0.1	1.3	2.8	4	3	3.2	3.5	5.4
China	1.1	1.8	n.a	0.3	0.5	1.5	2.1	3.7
Mexico	0	0	<0.1	<0.1	<0.1	<0.1	n.a	0.1
Spain	0	0	<0.1	<0.1	<0.1	<0.1	n.a	0.1
United States	1.5	8.1	20.5	28.7	30.3	35.7	39.0	47.6
Brazil	0	0	0	0	0	0	0	5.0
Paraguay	0	0	0	0	0	0	0	1.2
India	0	0	0	0	0	0	0	0.5
South Africa	0	0	0	0	0	0	0	0.5
Uruguay	0	0	0	0	0	0	0	0.3
Philippines	0	0	0	0	0	0	0	0.1
Romania	0	0	0	0	0	0	0	0.1
World	2.8	12.8	27.8	39.9	44.2	52.6	58.7	81.0

Source: Devlin, Andrew (2003). An Overview of Biotechnology Statistics In Selected Countries. Paris: OECD DSTI/DOC (2003) 13 and datas for 2004 added from ISAAA Briefs (James, 2004)

In 2004, the global market value of biotech crops, was $4.70 billion representing 15% of the $32.5 billion global crop protection market in 2003 and 16% of the $30 billion global commercial seed market. The market value of the global biotech crop market is based on the sale price of biotech seed plus any technology fees that apply. The accumulated global value for the nine year period 1996 to 2004, since biotech crops were first commercialized in 1996, is $24 billion. The global value of the biotech crop market is projected at more than $5 billion for 2005 (James, 2004).

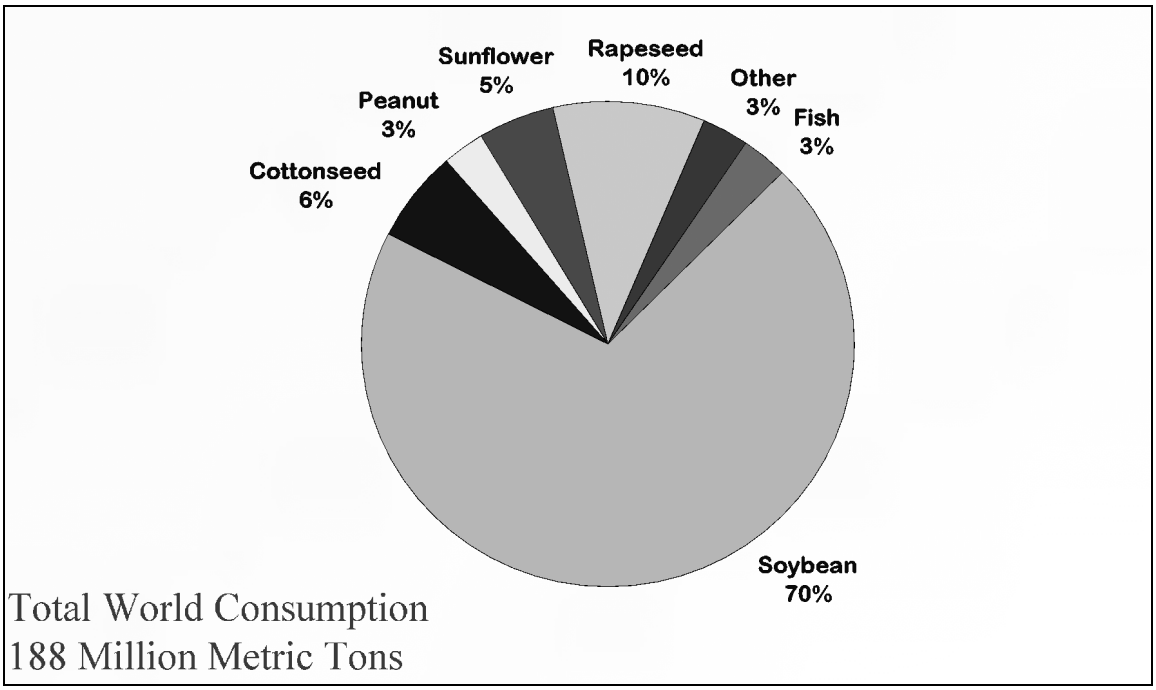
Unfotunately market analysis for genetically modified crops are not available publicly but analysis for soybean provide some empirical evidence for whole picture. As cited in the briefing paper of European Federation of Biotechnology soybean usage can be broadly

broken down into food, industrial and animal feed usesas whole beans, soya meal and soya oil. World's %60 of total oil production and %70 of total protein consumption is composed of soybean as showed in Figure 3.10 and 3.11 (Nill, 2004).



Source: American Soybean Association (ASA), 2004

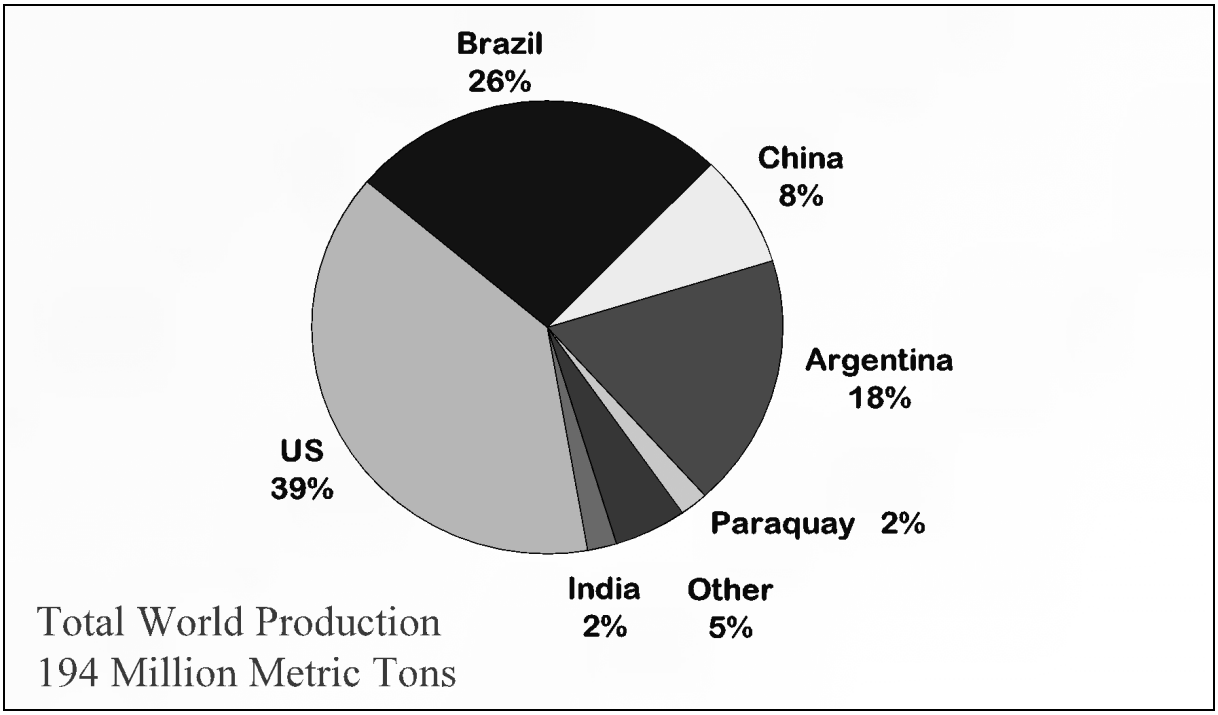
Figure 3.10. World Oilseed Production



Source: ASA, 2004

Figure 3.11. Protein Meal Consumption

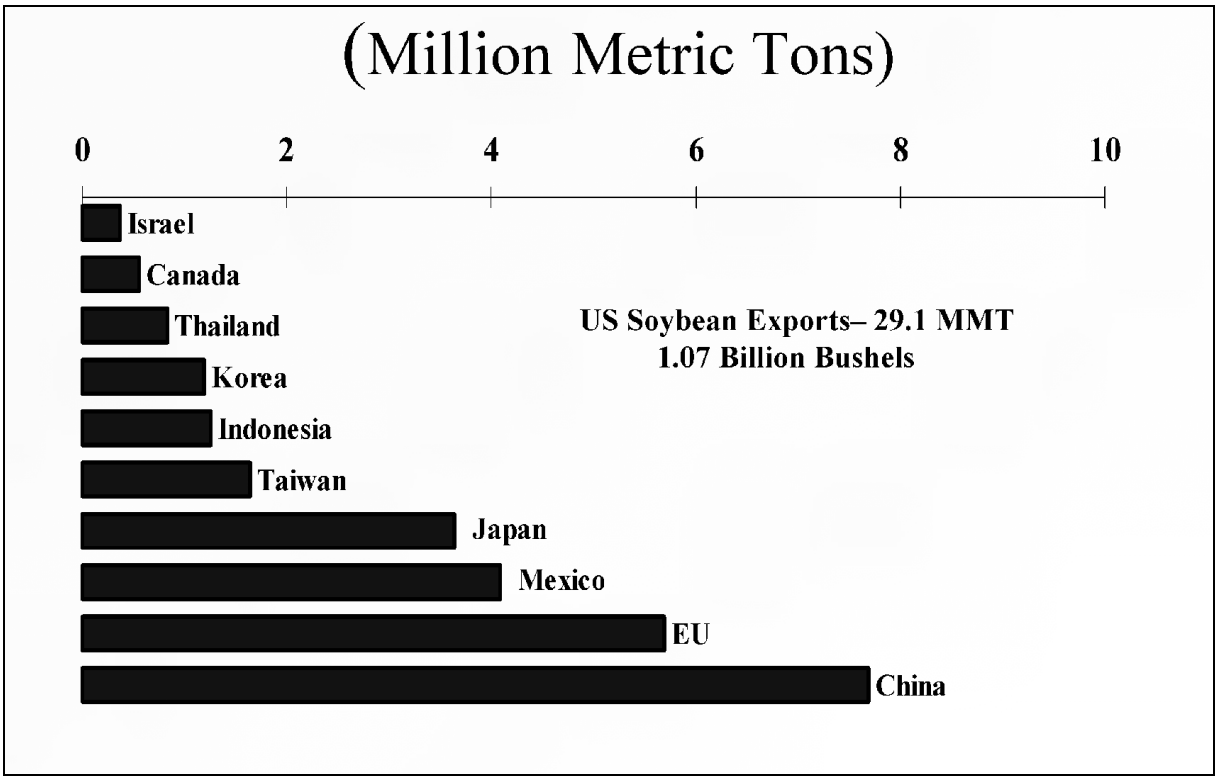
The briefing paper continues as, within the E.U., animal feed dominates total usage of meals (about %95 of total soya protein usage). Meal derived from oilseeds are widely used as an ingredient of animal feed mainly as a source of protein and oil meals derived from soya are considered to eb a necessary ingredient in certain compound feeds. Total annual of soya meal in the E.U. is about 27-28 million tonnes of which 25.5-26.5 million tonnes are used in animal feed. Over 50 million tonnes of protein material annually are used in the E.U. animal feed manufacturing of which about half is soya meal and the main reason for the dominance of soya meal is its relatively high protein content of %44-%50. Almost all E.U. soya meal used is imported either directly as meal or as beans crushed in the E.U. The main sources of supply are the U.S. (mainly as beans), Brazil and Argentina (both beans and meal) (EFB, 2002). Figure 3.12 below shows the major countries and what market percentage they supply in world trade, and further magnifies the role the US plays in world soybean trade.



Source:ASA, 2004

Figure 3.12. Major Soybean Producers

Currently the US is the number one exporter of soybeans in the world, and the E.U. have a considerable share as an major importer (Figure 3.13).



Source:ASA, 2004

Figure 3.13. US Soybean Export Customers

Last year alone, the US exported over $1,167 billion USD worth of soybeans to the EU[20]. However, this number has declined from 2.1 billion in 1996 as the E.U. Member States banned the U.S. orginated soybean exports for safety concerns and the EU has sought to import non-biotech varieties from other sources (Aheam, 2003). Also US exports dropped from 26 million tonnes in 1997 to 20 million tonnes in 1998. Consequently, the U.S. as the number one exporter of soybeans and the E.U. as the one of the major customer of the U.S. soybean exports, the US has a significant interest in maintaining market access for bioengineered crops to the EU.

By the approval of provisions under the E.U. regulations which are related with GMOs, all US companies began to be responsible for installing labelling and traceability systems if they want to continue exporting both non-GM soybeans and RoundupReady soybeans; therefore the dispute have the potential to damage other, traditional US agricultural exports. RoundupReady soybeans are which embodies a built-in immunity to

[20] US Census Bureau. *Foreign Trade Statistics. www.census.gov/foreign-trade/statistics*

herbicide glyphosate, thereby enabling farmers to reduce production costs when cultivating soybeans. Farmers across the U.S. began planting and cultivating RoundupReady soybean crops on a large scale commercial basis in 1996 and the E.U. began importing RoundupReady soybeans in the fall 1996 by the European Commission approval. After 1997, as explained by detail before in the literature review section, US exports of genetically modified soybeans (also other genetically modified foods/crops) banned by Member States. Now there is 18 approved GMO products for different uses under Directive 2001/18/EC (previously 90/220/EC) as of March 2001. 24 applications for the placing on the market of GMOs have been submitted into the authorization procedure under Directive 2001/18/EC. Products from 16 GMOs can legally be marketed in the E.U. by year 2004.

When trade and production statistics for soybeans in the U.S. which %70 of production includes genetically modified soybeans and the E.U.'s share in the U.S. soybean exports are in consider, the provisions approved under the E.U. legislation is a significant blow to the U.S. exports. These regulations are with protectionist approach or not it is clear that by trade-restricting regulatory responses of the E.U., the U.S. foreign trade effected a lot so it worked from this point of view. Another consideration is, if these trade barriers worked for domestic producers or not. Safety measures of the E.U. with respect to precautionary principle also put significant difficulties for internal market, yet number of approvals to marketable genetically modified products is also very low inside the E.U.

3.4.2. Comparing Regulatory Approaches to GMOs

As mentioned before, the U.S. and the E.U. regulatory approaches differs from three aspects. The first one is product-based vs. process-based regulatory approach, secondly risk assessment issues and last labelling issues.

The US has assigned a science-based approach towards the regulation of new GMOs, labeling requirements and how GMOs are to be considered. Three governmental agencies oversee the regulation of GMOs according to type. Genetically modified plants

are regulated by the UDSA's Animal and Plant Health Inspection Service (APHIS), which requires that a permit and notification be given for new crops (Sheldon, 2002). Genetically modified plants that express pesticides such as *Bacillus Thuringiensis (Bt)* and novel microorganisms are regulated by the US Environmental Protection Agency. The US Food and Drug Administration (FDA) handles pre-market approval of GMOs of foods containing GM ingredients, food additives, veterinarian and human drugs, feed and labeling issues (Faust, 2002). It is the FDA, which in accordance with the Food Drug and Cosmetic Act (FD&C Act) deemed labeling unnecessary given that GMOs were not considered to be different than traditional crops.

Examining the logic behind the no labeling decision put forth by the FDA is important to review in more detail, as this decision is likely to be central to any trade violation argument the U.S. puts forward (see Figure 1). The FDA addressed general labeling in 1992, specifically under section 403(a), where it was decided that the common name must be used, and all facts that are "material" must be detailed. Materiality relates to information about the attributes of a food that pose a health risk, or about which nutritional claims are made. The FDA's stand was that GMO labeling was not necessary on the following grounds. Firstly, the FDA viewed GMOs as a molecular extension of classic plant breeding methods, so this does not constitute "material" information. Secondly, the FDA established the principle that GM foods were not different than those developed traditionally. Therefore, given their substantial equivalence, GMOs would only require labeling if they contained allergens, or if they were substantially different, and therefore had different nutritional characteristics (Sheldon, 2002).

The EU has undertaken a different approach to regulating GMOs, characterized by the precautionary principle. Between 1992 and April 1998, the EU approved 10 genetically modified products based on legislation 90/219/EEC and 90/220/EEC written by the DG XI for Environment and Consumer Protection. Council Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms is the first binding piece of legislation regarding GMOs and it was approved in 1990. This directive replaced by 2001/18/EC in 2001 which introduces principles fort he environmental risk assessment. These principles include mandatory post-market monitoring requirements, including on long-term effects associated with the interaction with other GMOs and the

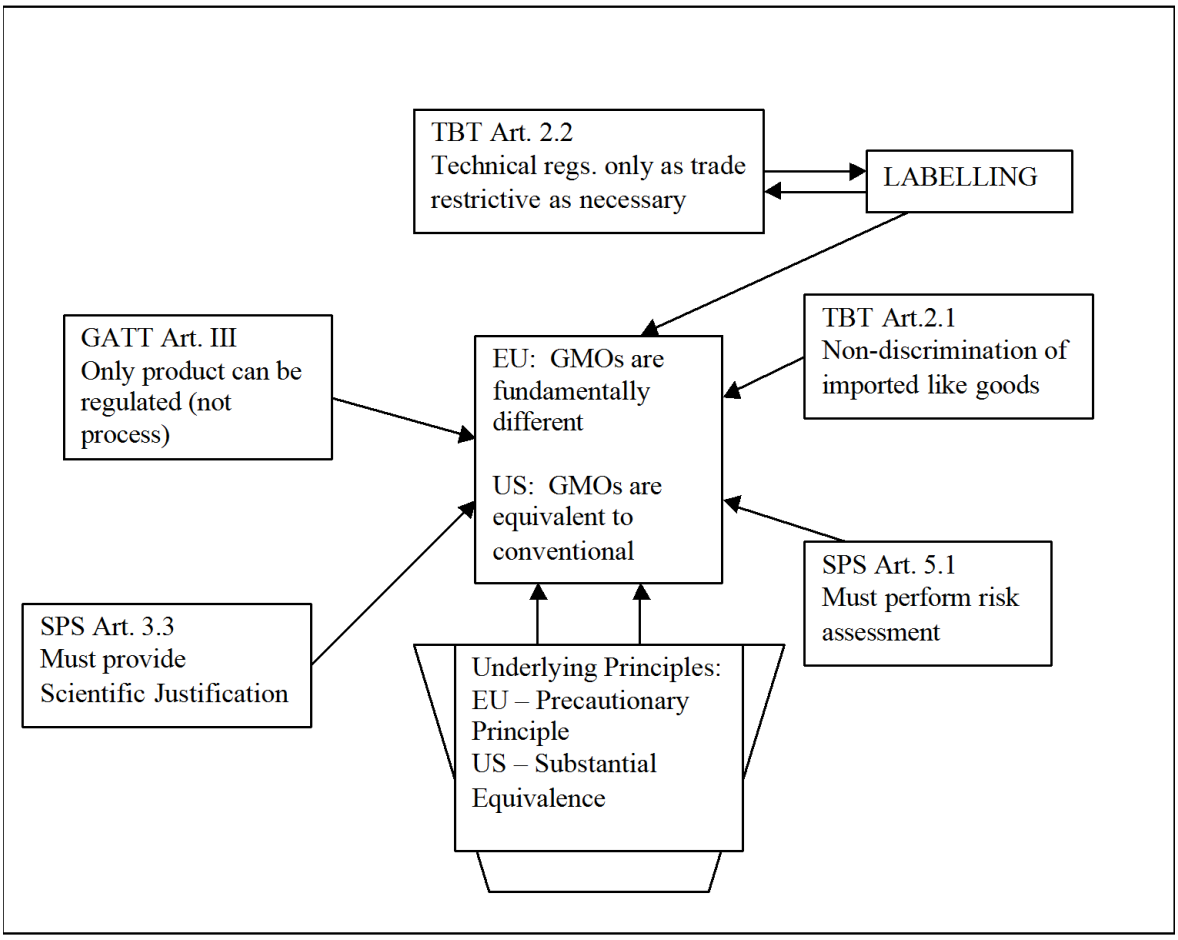
environment; mandatory information to the public; information to allow the identification and detection of GMOs to facilitate post-market inspection and control. According to the last principle first approvals for the release of GMOs to be limited to a maximum of ten years. Under Directive 2001/18, the application must include a full environmental risk assessment. Other than this directive also directives 90/219, 98/81 and regulations 1829/2003, 1830/2003, 641/2004 are realated with GMO issues.

Regulation 1829/2003 on genetically modified food and feed regulates the placing on the market of food and feed products containing or consisting of GMOs and also provides fort he labelling of such products to the final consumer. The regulation ensures that experiences such as with Starlink maize in the U.S. (a genetically modified maize which was only authorised for feed but turned up in food) are avoided because GMOs likely to be used as food and feed can only be authorized for both uses, or not at all.

Regulation 1830/2003 on traceability and labelling of GMOs and traceability of food and feed products from GMOs introduces a system to trace and label GMOs and to trace food and feed products produced from GMOs. Traceability can be defined as the ability to trace products through the production and distribution line. The Regulation covers all GMOs that have received EU authorisation for the placing on the market, that is all products, including food and feed, containing or consisting of GMOs. All food, including soya or maize oil produced from GM soya and maize, and food ingredients, such as biscuits with maize oil produced from GM maize must be labelled. The label has to indicate “This product contains genetically modified organisms” or “produced form genetically modified (name of organism)”.

The differences between the regulations and the E.U.’s restrictions to the U.S. exports due to lack of labelling of products and as a result of precautionary principle approach of the E.U. trade dispute between the two took place within the WTO regulatory framework. Opposition of the U.S. (also Canada, Argentina, Australia, Barazil, Chile, Columbia, India, Mexico, New Zeland and Peru requested consultations with the same bases) to trade restrictions of the E.U. for GMO included products and its submissions made under GATT rules, the SPS and the TBT Agreement which are discussed in more

detail before in the literature review section and also summerised in the Figure 3.14. The case has not been concluded yet.



Source: Callender,Tova (2003). Analysis of the Possible EU-US Trade Dispute over the EUs GMO Approval Moratorium and New GMO Labeling Directive, ESM246

Figure 3.14. Schematic of factors affecting the possible EU-US WTO GMO case

In summary, the differences between the US and the EU approach to regulating GM foods are sharply contrasting. The US relies on a scientific, risk-based approach where presumed substantial equivalence of foods leads to the conclusion that GMOs require no labeling. In contrast, the EU adheres to the precautionary principle, speculating that there are possible long-term risks associated with GMOs, and as a result, risk-assessment of GMOs cannot be treated as conclusive. The EU therefore asserts that regulatory authorities should not allow the release of GMOs into the environment, and as they are not proven to be equivalent to the conventional counterpart, guidelines and mandatory labeling on such foods should be required.

As Sindico (2005) mentioned, the E.U. stressed its poistion in precautionary principle as;

> *"The precautionary principle is already, in the view of the European Communities, a general customary rule of international law or at least a general principle of law, the essenceof which is that it applies not only in the management of a risk, but also in the assessment thereof."(WTO, 1998)*

The E.U. considered that the precautionary principle is refered to the implementation of a measure. On the other hand, the U.S. have a completely opposite view about the precautionary principle. According to its position, it is not a principle but just an approach;

> *"The U.S. does not consider that the precautionary principle represents a principle of customary international law rather, it may be characterized as an approach- the content of which may very from context to context."(WTO, 1998)*

In accordance with these opnions it should be noted that science base risk assessment, science based risk management and science based risk analysis sometimes not equal to science based decisions. If GM product is more beneficial (productivity, cost effectiveness, nutritional quality, etc) than the non-modified source and is not more risky it will come to market sooner or later. This "sooner or later" depends upon regulatory approach chosen (Golikov, 2003).

3.4.3. Sitution in Turkey

Although trade and production of GMOs are restricted in Turkey, it is a member of the Cartagena Protocol. From this side Turkey's approach is close to the E.U with one difference. The E.U. restricted the trade of GMOs with respect to the precautionary principle but continue field trials and although it is much more lower than the U.S., it also continue develop new products as seen from its patent applications. The Turkey's perception of biotechnology is much more similar to the given example for Ethiopia in Table 2.3; product is unsafe even if not developed yet. When some research made under GMO related subjects the only thing that the researcher find is the strong opposition of some consumer or environmental groups.

3.5. Statistical Comparison of Venture Capital and Dedicated Biotechnology Firms

Till this section, the indicators compared are parallel to the issues which take part in the literature review section. Culture collections compared as they correspond to development level of countries in terms of resource capacity and infrastructure for industrial needs. Different strategies for IPR protection in the context of biodiversity and biotechnology from legislative perspective issued and patent comparisons made due to they indicate the success of policy strategy in biotech related IPR protection. GMO regulations and trade facts compared to show again different approaches of the countries. The evolution of biotechnology and biotechnology based sectors is accompanied by an evolution in policy making strategy regarding biotechnology like summarized above. However, scope of biotech policies are not limited with these issues although they are the main issues in concern of policy makers and industry. Competitiveness analysis in biotechnolgy is also complementary to find if a policy strategy is successful or not because market related facts show functionality of a policy. But to collect market datas is very hard due to the multidiciplinary structure of biotech industry[21]. Although market surveys on various aspects on biotech have been published, they range in price from a few hundred dollors to over USD 25.000 depending on their scope. Thus, some publicly available statistical data collected (venture capital and dedicated biotechnology firms), but they are consequents of policy approaches rather than factors of policy strategies.

3.5.1. Biotechnology and Venture Capital

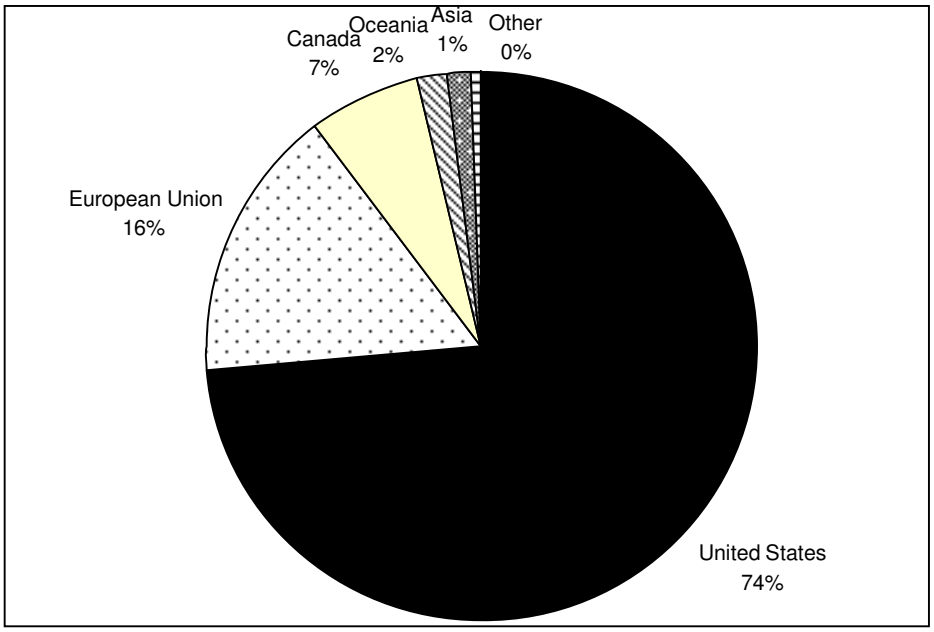
Biotechnology was first commercialized in the U.S. in the mid 1970s. Because of the factors like uncertainty about regulation and patenting and the E.U.'s attempts to try and develop policies acceptable to member states with very differing approaches to these issues, a similar progress can not be reached in the E.U (Senker, 1998). Evolution of the biotechnology related industries in the U.S. by the new breakthroughs in 1970s started by

[21] See industrial classification of biotech on page 9.

the Genentech in 1976-the first venture capital biotechnology company. Senker mentioned this as,

> *"The example of Genentech led to the birth of the biotechnology industry in the U.S, with an explosion of small firms led by academic entrepreneurs who retained close links with their academic base. Early start-up funds were provided by venture capitalists. Venture capital is an American phenomenon which supplies risk capital to new companies based on scientific research. In 1979 there were 250 US venture capital firms, but very few in Europe, except for a handful in the U:K."*

Linkages between venture capital and university scientists in a culture which encouraged a close relationship between university science and industry and supported entrepreneurship played a key role in the development of US biotech industry (Senker, 1998). Venture capital is a high risk fund-raising technique for companies wanting to exchange equity for capital. Today the U.S. still remais the market for venture capital for biotechnology firms. In 2001, biotechnology venture capital in the United States amounted to USD 3.419 million which accounted for 74% of biotechnology venture capital investment in the OECD. By comparison, biotechnology venture capital in Europe amounted only to USD 745 million (16%) (Figure 3.15).



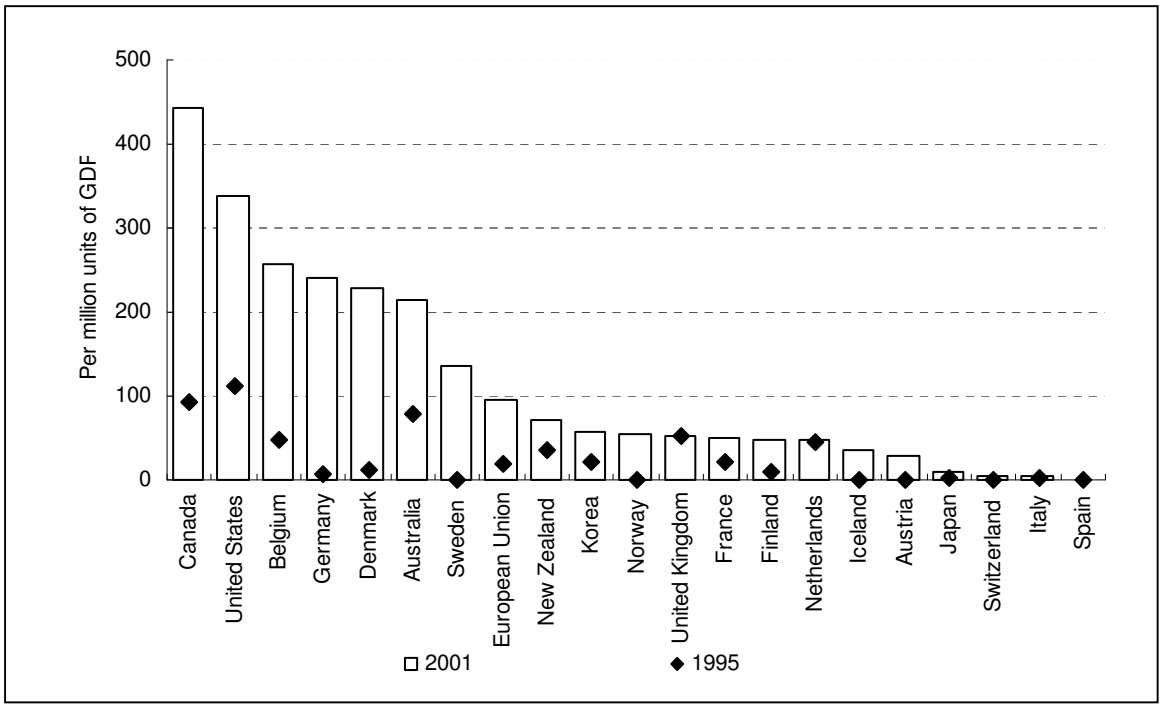
Source: Devlin, Andrew (2003). *An Overview of Biotechnology Statistics In Selected Countries*. Paris: OECD DSTI/DOC (2003) 13[22]

Figure 3.15. Biotechnology venture capital investment shares in 2001

[22] The data used for the following graphs and accompanying analysis are mainly drawn from four sources: The US National Venture Capital Association (NVCA), the European Venture Capital Association (EVCA), the Canadian Venture Capital Association (CVCA) and the Asian Venture Capital Journal (AVCJ). Unfortunately, information on venture capital investments in Asia does not allow the separate identification of biotechnology in the overall medical sector.

According to the OECD report the main European contributor to biotechnology venture capital investment is Germany (60% of the EU total). Germany is followed by the United Kingdom (10%) and France (9%) respectively.

When biotechnology venture capital expressed per million units of GDP the U.S. have a considerable increase between the years 1995 and 2001 and in it have the second highest ratio in year 2001 (Figure 3.16)

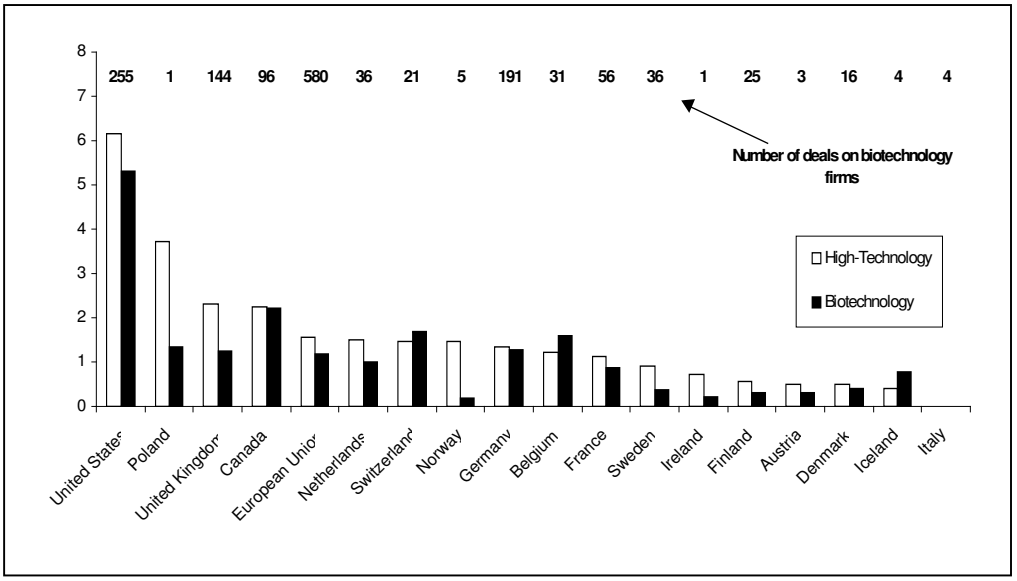


Source: Devlin, Andrew (2003). *An Overview of Biotechnology Statistics In Selected Countries*. Paris: OECD DSTI/DOC (2003) 13[23]

Figure 3.16. Biotechnology venture capital investment per million units of GDP, 1995 and 2001

In the United States, the average biotechnology deal represented USD 5.3 million, more than double the amount in Canada and more than four times that in the European Union (Figure 3.17). The European aggregate hides large differences: in 1999, the largest numbers of biotechnology venture capital deals were in Germany (191), the United Kingdom (144) and France (56), but the average amounts of the deals were USD 2.5 million, USD 0.8 million and USD 5.8 million, respectively.

[23] Sources for collected datas:The *European Venture Capital Association* for European countries, the *Asian Venture Capital Journal* (Yearbook) for Australia, New Zealand, Japan and Korea and the *National Venture Capital Association f*or the United States.



Source: van Beuzekom, Bridget (2001). Biotechnology Statistics in OECD Member Countries:Compendium of Existing National Statistics. Paris:OECD DSTI/DOC (2001) 6[24]

Figure 3.17. Average size of venture capital investment deals by sector, USD millions, 1999

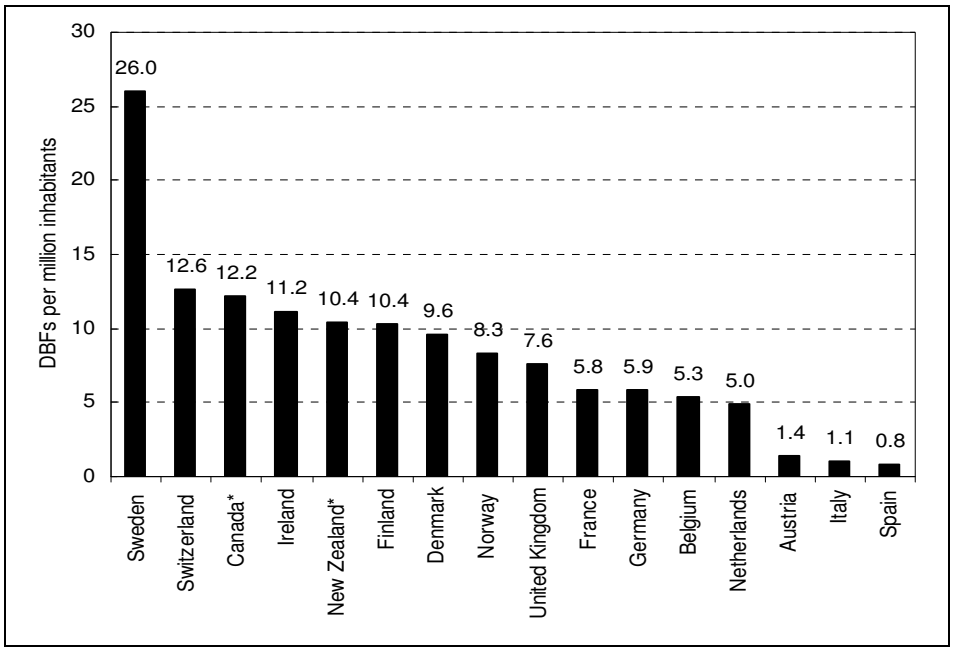
Senker (1998) explains the E.U.'s hesitation to exploit biotech, lack of venture capital, an underdeveloped science base, lack of knowledge of the new technology and its commercial potential by existing firms and compared with the U.S., a rather negative attitude to industry by European academics. The lack of developed capital markets for technology like in the U.S. which was already active in the begining of the 20th century, creates important barriers for prospective venture capitalists. Venture capital provides finance to prospective academic entrepreneurs, provides managerial advice, organisational capabilities and signals to prospective investors about the potential of the new company. Thus, venture capital mixes technology, academia and finance. Lack of a developed venture capital market has restricted the start-up of biotechnology firms in the E.U. (Allansdottir, Bonaccorsi, Gamberdella, Mariani, Orsenigo, Pammoli and Riccaboni, 2002).

[24] *Source*: For the United States, National Science Foundation, *Science and Engineering Indicators 2000* (also accessible at www.nsf.gov). For the European Union, EVCA Yearbook 2000 (www.evca.com). For Canada, CVCA (www.cvca.ca).

3.5.2. Dedicated Biotechnology Firms (DBFs)

The U.S. biotechnology firms started emerging in the second half of the 1970s, initially in the form of DBFs and now the European DBFs are hardly comparable with the American biotechnology firms because this sector remains underdeveloped. Dedicated biotechnology firms are defined as "core biotechnology firms". These firms specialise in biotechnology products and process development, or are specialised suppliers. As biotechnology highlights the importance of firms capabilities, the role of DBFs are become more clearer as small specialised firms. They enter the industry with the explicit aim of exploiting the new technologies of life sciences for different industrial purposes and they have remarkable and radical impact on pharmaceuticals and agriculture (Allansdottir, Bonaccorsi, Gamberdella, Mariani, Orsenigo, Pammoli and Riccaboni, 2002).

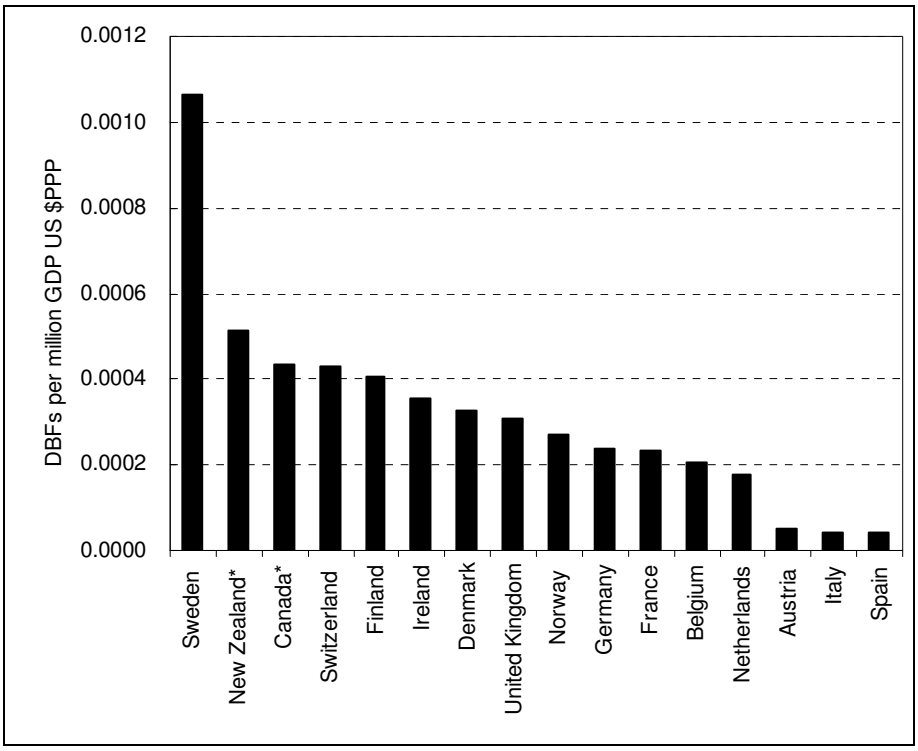
Figure 3.18 and 3.19 show the number of DBFs per inhabitant and per GDP in major European countries and some others at the end of the year 2000. When numbers of DBFs calibrated using population or GDP, Sweden ranked first according to both measures followed by Switzerland, Ireland, Finland and Denmark. The UK, Germany and France have similar values while Italy and Spain have the lowest ratios.



Source: Devlin, Andrew (2003). *An Overview of Biotechnology Statistics In Selected Countries*. Paris: OECD DSTI/DOC (2003) 13[25]

Figure 3.18. Dedicated biotechnology firms per million inhabitants, 2000

[25] *Source:* Biotechnology Industry database, University of Siena, Statistics Canada, Statistics New Zealand. *The University of Siena is the source for all countries except for Canada and New Zealand.



Source: Devlin, Andrew (2003). *An Overview of Biotechnology Statistics In Selected Countries*. Paris: OECD DSTI/DOC (2003) 13[26]

Figure 3.19. Dedicated biotechnology firms per million GDP USD PPP, 2000

Companies such as Genentech, Cetus and Biogen in the U.S. were established in the 1970s but were followed by many others at the turn of the decade with the total population of small dedicated biotechnology firms (DBFs) growing from 50 in 1978 to approximately 500 by 1984 and 700 by 1987 after which the population has remained relatively stable. Many were spin-offs from academic laboratories, offering researchers both first class facilities in which to pursue their scientific interests and a chance, through stock options, to make themselves considerable wealth when the firm went public and launched its shares on the stock exchange (Sharp, 1996). It is argued that the advantage of the U.S. grow out of the U.S. in general is just more risk accepting and interested in novelty. Academics are very entrepreneurial and well supported by venture capital, which makes it easy for scientists to get investments for their companies and scientists regard working in DBFs as an attractive career option. The main problems of the E.U.'s DBFs sector are lack of venture capital and poor capability of academics in commercializing their work (Senker, Joly and Reinhard, 1998).

[26] *Sources:* Biotechnology Industry Database, University of Siena, Statistics Canada, Statistics New Zealand.
*The source is University of Siena for all countries except for Canada and New Zealand.

IV. CONCLUSION

Policy is a result of several desicions of public authorities with respect to the approach followed. Decisions are the key determinants of policy strategies and in this thesis for an objective comparison of the U.S. and the E.U. biotechnology policies and approaches, related decisions of the U.S. and the E.U. authorities from different concerning areas analysed systematically. Compareable analysis done by both quantitative and qualitative indicators that include, regulations, both national, regional and international level, related with genetic resource access, technology transfer, patentable subject matter and GMOs. Results show that the U.S. approach and the E.U. approach is pretty differs.

When biotechnology is in concern it can be said that the U.S. following a radical policy than its competitors. Decisions taken upto date, although they are in different areas of interest, are not independent from each other and they are only for one goal. When increasing competition, free trade trends in international trade and protectionist approaches followed against free trade is in consideration, the U.S. approach is not different than increasing competitiveness. Because of that reason the U.S. differentiated the technology transfer fact with its applications and turn it to its own benefit because technology transfer means loss of competititveness and the U.S. has no toleration to this. Thus, we can not see the U.S. as a Party of any international agreement which jeopardize its producer or industry. If this agreement envisages tachnology transfer that does not comply with its principles it will be the only country which did not sign it through 188 countries. In another situation, if protection of inventions is in concider, this time it pioneers an international agreement with strong lobby, like TRIPs.

While everyone is discussing ethical concerns about patenting plant varieties, although some of the interests based on real concern, mostly they are reflection of protectionist policies; legislation is already become appropriate for plant variety patents. Such a dangerous tool like regulation is already become a supportive tool that the only

thing fot the investor or inventor is to create and design a product, because it is going to have a patent in any case if it has an industrial application. It should be noted that what is discussed about is not the truth or falsity of the policy, it is the success of the policy.

It seems that competitiveness could not be increased by protectionist approach, by making internal market restricted for foreign trade as understood from E.U.'s GMO experience. Indeed it is not the decisions that caused to failure or ineffectiveness of the biotechnology policy, it is caused due to not reach a common decision and determine real targets within the E.U. It would take a really considerable time for the E.U. even GMO production become free, the same strict policy is followed in the area of intellectual property right and instead of increasing competitiveness, catching up the same level of the U.S.in an optimal time is aimed. While the first steps taken to establish todays multinational companies in the U.S. in 1970s, the E.U. realised the fact of biotechnology in 1990s. Therefore from the side of real market, from the side of policy makers or from the side of public, perception of biotechnology is rather different than any other country.

In the case of Turkey, the outlook from the side of biotechnology shows that Turkey is well below its potential. R&D efforts, funds and trained personnel are not taken into consideration at all during analysing Turkey's situation. It should be noted that money is not for technology, technology is for making money. We might describe biotech as making money with biology because without the discline of the market place there might indeed be elegant science but there would be no technology. Problem that Turkey face is not the amount of funds, it is flow of funds into wrong projects instead of the appropriate projects. If efforts are not enough for conservation of biological resource conservation, storing them and identification of them in a very bioresource rich country, if right connections can not established between industry and academia, if funds can be spent for projects that do not have exact benefit on behalf of the country then the problem is not the amount of funds, it is the absence of right strategy. In Turkey there are 72 universities, therefore it can not be said that there is a lack of trained personnel in Turkey, but again because right connections can not be established, knowledge can not be transformed to a marketable product, if it can be transformed it can not be protected, biotechnology policy is not something more than a phrase in Turkey. Therefore what should be done in Turkey can be listed as,

1. to know and apply technology management in an effective manner
2. to make legislative procedures appropriate for effective technology management and avoid from over regulation
3. to aim policies that support initiatives and investors
4. to understand the advantages of biodiversity richness and use them in an appropriate way, restrict biopiracy
5. to establish qualified culture collections that conserve, store and identfy bioresources,
6. to know the systematic of technology production
7. to replace realities and current applications rather than popular speculatives to stop biotechnofobia; train philosofers of applied ethics, publish articles or books in native language.

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ANNEX 1

HISTORICAL DEVELOPMENT OF BIOTECHNOLOGY

ANNEX 1

HISTORICAL DEVELOPMENT OF BIOTECHNOLOGY

1. Biotechnological production of foods and beverages
Sumarians and Babylonians were drinking beer by 6000 B.C.; Egyptians were baking leavened bread by 4000 B.C.; wine was known in the Near East by the time the bool of Genesis was written. Microorganisms first seen in seventeenth century by Antonie van Leeuwenhoek, who developed the simple microscope; fermentatice ability of biotechnology; cheese production has ancient origins; so also has mushroom cultivation.
2. Biotechnological process initially developed under non-sterile conditions
Ethanol, acetic acid, butanol and acetone were produced by the end of the nineteenth century by open microbial fermentaition processes; waste water treatment and municipal composting of solid wastes were the largest fermentation capacity practised throughout the world.
3. Introduction of sterility to biotechnological processes
In the 1940's complicated engineering techniques were introduced to the mass cultivation of microorganisms to exclude contaminating microorganisms. Examples include antibiotics, amino acids, organic acids, enzymes, steroids, polysaccharides, vaccines and monoclonal antibodies.
4. Applied genetics and recombinant DNA technology
Traditional strain improvement of important industrial organisms has long been practised; rDNA techniques together with protoplast fusion allow new programming of the biological properties of organisms

ANNEX 2

THE MAIN AREAS OF APPLICATION OF BIOTECHNOLOGY

ANNEX 2

THE MAIN AREAS OF APPLICATION OF BIOTECHNOLOGY

Bioprocess technology
Historically, the most important area of biotechnology, namely brewing, antibiotics, mammalian cell culture, etc.; extensive development in progress with new products envisaged, namely polysaccharides, medically important drugs, solvents, protein-enhanced foods. Novel fermenter designs to optimise productivity.

Enzyme technology
Used for the catalysis of extremely specific chemical reactions; immobilization of enzymes; to create specific molecular converters (bioreactors). Products formed include L-amino acids, high fructose syrup, semi-synthetic penicillins, starch and cellulose hydrolysis, etc. Enzyme probes for bioassays

Waste technology
Long historical importance but more emphasis now being made to couple these processes with the conservation and recycling of resources; foods and fertilisers, biological fuels.

Environmental technology
Great scope exists for the application of biotechnological concepts for solving many environmental problems - pollution control, removing toxic wastes; recovery of metals from mining wastes and low-grade ores.

Renewable resources technology
The use of renewable energy sources, in particular, lignocellulose to generate new sources of chemical raw materials and energy ethanol, methane and hydrogen. Total utilizations of plant and animal material.

Plant and animal agriculture
Genetically engineered plants to improve nutrition, disease resistance, keeping quality, improved yield and stress tolerance will become increasingly commercially available. Improved productivity, etc., for animal farming. Improved food quality, flavour, taste and microbial safety.

Healthcare
New drugs and better treatment for delivering medicines to diseased parts. Improved disease diagnosis, understanding of the human genome.

ANNEX 3

DEFINITION LIST OF BIOTECHNOLOGY IN OECD MEMBER AND OBSERVER STATES

ANNEX 3

DEFINITION LIST OF BIOTECHNOLOGY IN OECD MEMBER AND OBSERVER STATES

COUNTRY	DEFINITION	SOURCE
AUSTRALIA	"Biotechnology" means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. Biotechnology is simply the use of micro-organisms, and plant and animal cells, to produce materials such as food, medicine and chemicals that are useful to mankind".	Department of Industry, Science and Resources (ISR) in association with Australian Biotechnology Association and Ernst & Young
AUSTRIA	NOT AVAİLABLE	
BELGIUM	N/A	
CANADA	Biotechnology is defined as "the application of science and engineering in the direct or indirect use of living organisms, in their natural or modified forms, in an innovative manner in the production of goods and services or to improve existing processes." Various modern biotechnological tools have been included under this definition, including DNA-based technologies, biochemistry, immunochemistry and a series of advanced bioprocessing based technologies.	BIOTECanada is the association representing companies and research organisations involved in all aspects of biotechnology in Canada.
CZECH REPUBLIC	N/A	
DENMARK	N/A	
FINLAND	Companies are divided into categories: Pharmaceuticals/Drug Development; Diagnostics; Biomaterials; Industrial enzymes; Environment; Food; Agro; Services.	Finnish Bioindustries
FRANCE	Rather than defining biotechnology France has established a list of 35 biotechnologies	MENRT (Ministère de l'éducation nationale, de la recherche et de la technologie – Bureau des études statistiques sur la recherche) and INRA/SERD (Institut National de la Recherche Agronomique)

COUNTRY	DEFINITION	SOURCE
GERMANY	"Biotechnological R&D is defined for the purposes of the survey as a systematic, creative work integrating biology, micro-biology, molecular biology and engineering sciences in order to utilise or to increase the potential of living organisms or their cellular or sub-cellular or molecular components for the development of products, processes and services. R&D in biotechnology was further subdivided into R&D in biotechnology (excluding genetic engineering) and R&D in genetic engineering."	Statistisches Bundesamt (Federal Statistical Office Germany)
GREECE	N/A	
HUNGARY	"For this project a rather broad understanding of biotechnology is used defining biotechnology as any technique that uses living organisms or parts thereof to make or modify products, to degrade substances to modify living organisms (plants, animals, micro-organisms) for specific uses, or for services (*e.g.* in analytical laboratories). Following this definition genetic engineering is not synonymous with biotechnology but rather one of the several methods which are used in biotechnology."	IKU (Innovation Research Centre) and FhGISI (Fraunhofer Institute for Systems and Innovation Research)
ICELAND	Rather than defining biotechnology Iceland has established a list of 14 biotechnologies:	The Icelandic Research Council
ISRAEL	N/A	
IRELAND	N/A	
ITALY	"Percentage of R&D activities (expenditure) related to biotechnologies".	National Institute of Statistics (ISTAT)
JAPAN	"Gene recombination research and development (recombinant DNA research and development) means research and development relating to creation of cells having new genetic traits by recombining with a gene of a different species after cutting and joining genes from certain organisms (DNA, deoxyribo nucleic acid, chemical substance of a gene), using oxygen, and then transplanting it into a cell of a different species of organism. The results can be applied to basic research and development and medicine, agriculture, industry, and energy and environmental protection."	Statistics Bureau, Management and Co-ordination Agency of the Government of Japan
KOREA	N/A	
LUXEMBURG	N/A	
MEXICO	N/A	
NETHERLANDS	Based on a classification of Field of Research and Technology developed by CBS: Research on genetic modification, cell fusion/biology, fermentation, development of proteins/enzymes, neuro biology, botanical improvement, bio catalyse.	Central Bureau of Statistics (CBS)

COUNTRY	DEFINITION	SOURCE
NEW ZELAND	Modern biotechnology is defined as: The application of scientific and engineering principles to the processing of material by biological agents and the processing of biological materials to improve the quality of life by isolating, modifying and synthesising the genetic instructions responsible for actual biological processes.	Ministry of Research, Science and Technology (MORST) and Statistics New Zealand (SNZ)
NORWAY	Biotechnology is the use of microorganisms, plants and animal cells for making or modification of products, plants and animals or the development of microorganisms for specific use. Biotechnology concerning "aquaculture" is included.	Statistics Norway (SSB) and Norwegian Institute for Studies in Research and Higher Education (NIFU).
POLAND	N/A	
PORUGAL	N/A	
SLOVAK REPUBLIC	N/A	
SOUTH AFRICA	N/A	
SPAIN	N/A	
SWEDEN	An analysis of the Swedish Biotechnology Innovation System, is being undertaken, by which is meant: *The actors that develop, produce, analyse or use biological systems on a micro-, cellular or molecular level and the public and private institutions that affect their behaviour.* The focus is on modern biotechnology and innovative use of classical biotechnology.	NUTEK (Swedish National Board for Industrial and Technical Development)
SWITZERLAND	Intend to use the official definition not yet determined by the OECD, followed by a list of possible activities in Biotechnology for the requested fields.	Swiss Federal Statistics office
TURKEY	N/A	
UNITED KINGDOM	Biotechnology is defined as the application of biological organisms, systems and processes to manufacturing or service industries.	Office of National Statistics (ONS)
UNITED STATES	The medical and industrial application of advanced genetic research toward the creation of new drugs, hormones, and other therapeutic items for both agricultural and human uses.	U.S. Census Bureau
EUROPEAN COMMISION	N/A	

Source: van Beuzekom, Bridget (2000). *Biotechnology Statistics in OECD Member Countries: An Inventory.* Paris: OECD DSTI/DOC (2000) 6

ANNEX 4

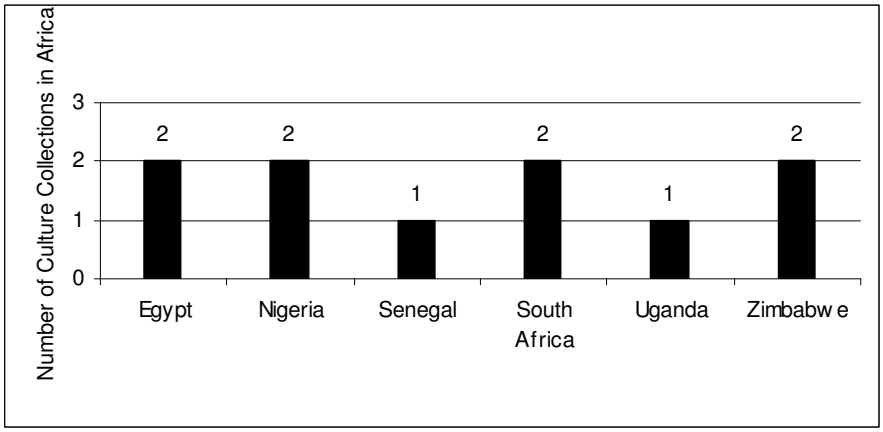
DISTRIBUTION OF CCs IN OTHER COUNTRIES

and

CULTURE NUMBERS IN REGISTERED COUNTRIES

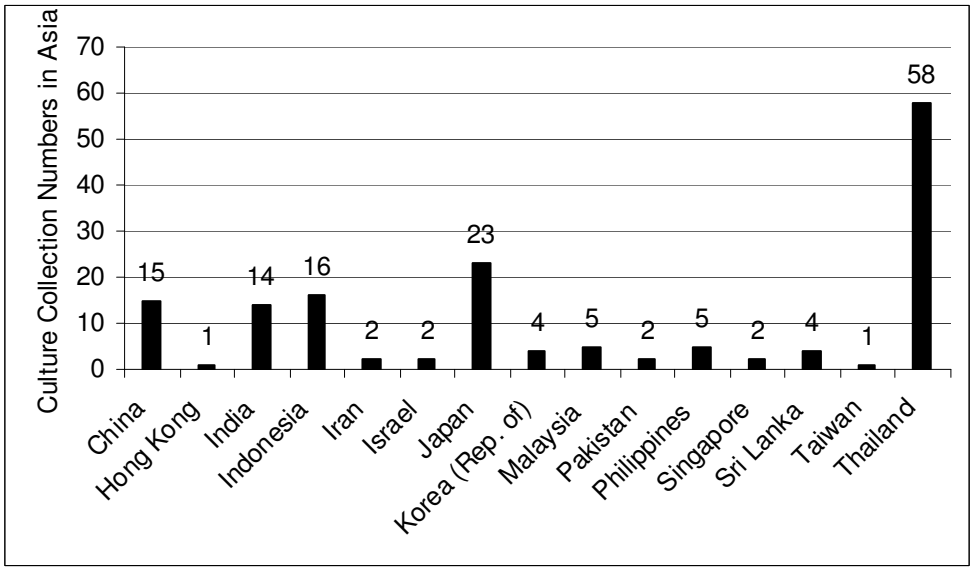
ANNEX 4

DISTRIBUTION OF CCs IN OTHER COUNTRIES



Source: Gürsoy, Nazlı & Özer, Ercüment (2003). *Türkiye'de ve Dünya'da Kültür Koleksiyonları Yeni Kapılar Açıyor.* Biyotek® Biyoteknoloji Sektör Dergisi, Volume 3 No:16, 33-37

1. Distribution of CCs in Africa



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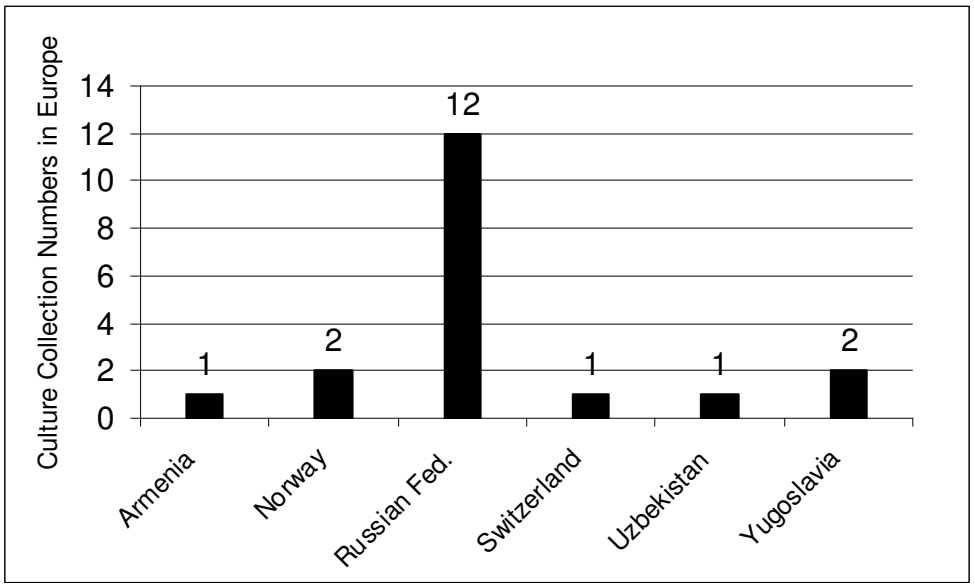
2. Distribution of CCs in Asia



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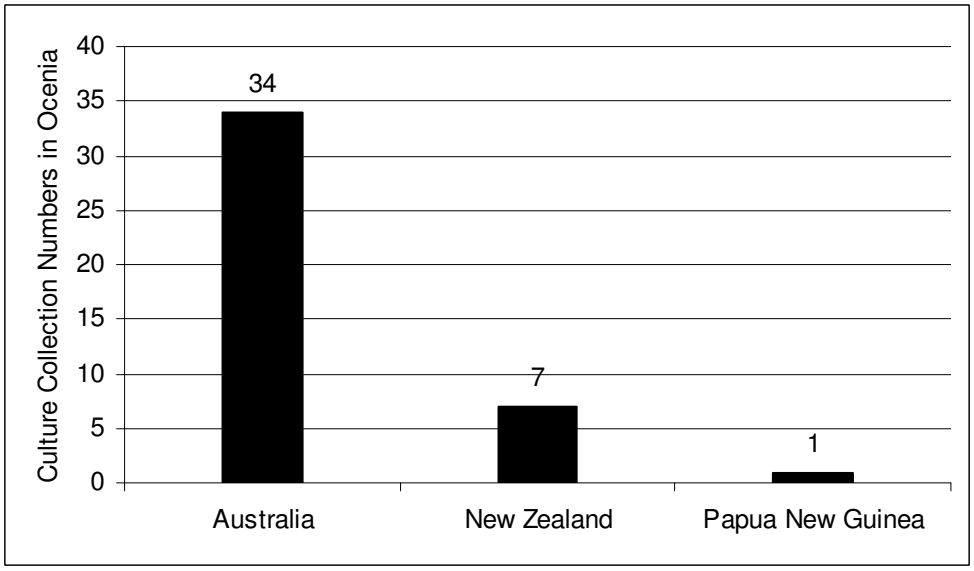
3. Distribution of CCs in Other European Countries



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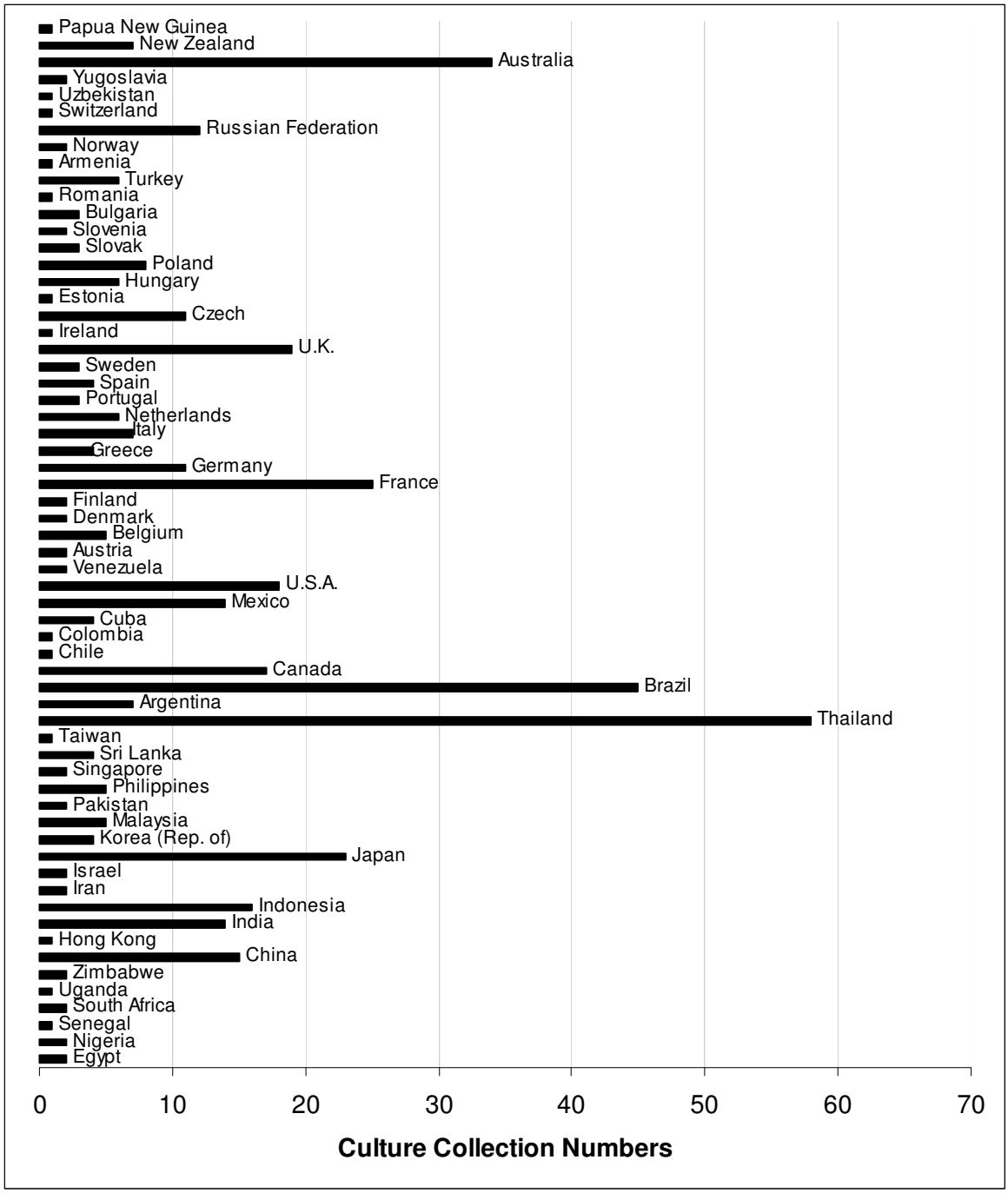
4. Distribution of CCs in Ocenia



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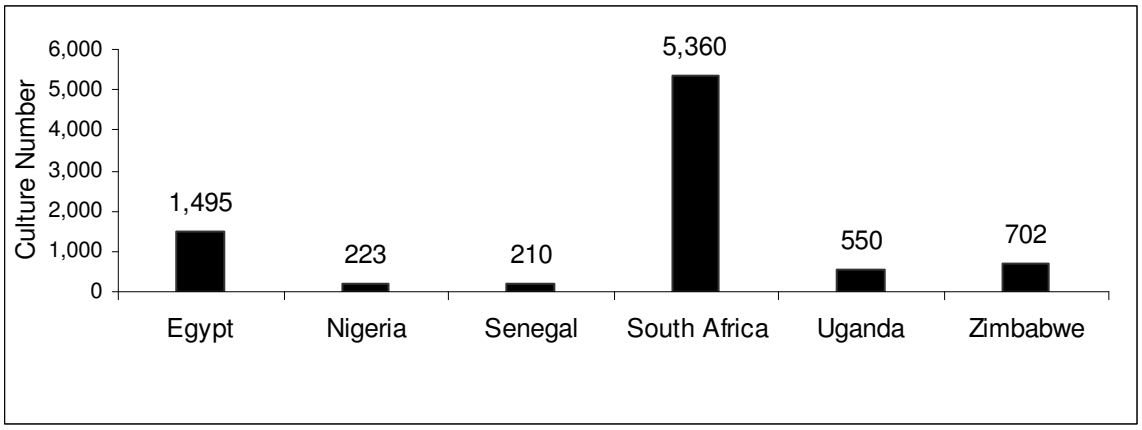
5. Culture Collection Numbers in the World Registered to WDCM

CULTURE NUMBERS IN REGISTERED COUNTRIES



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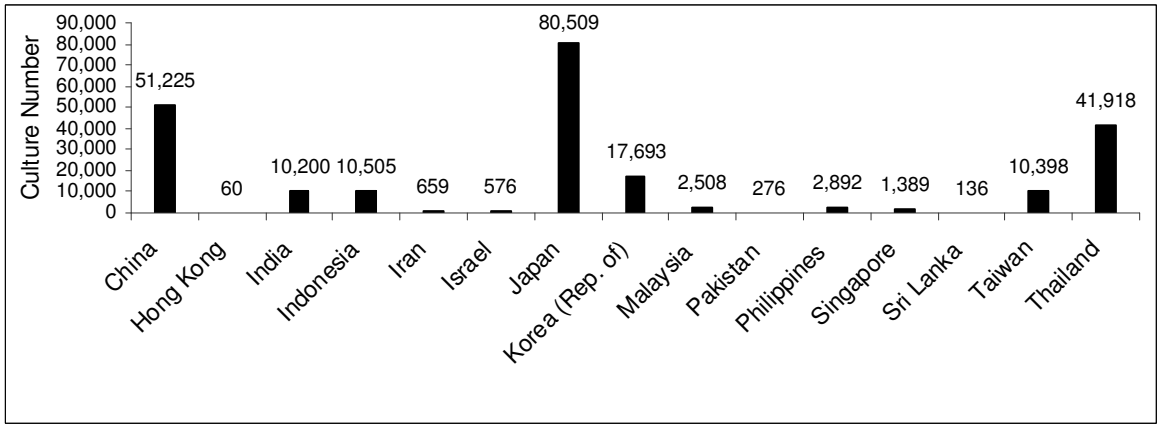
6. Culture Numbers in Africa



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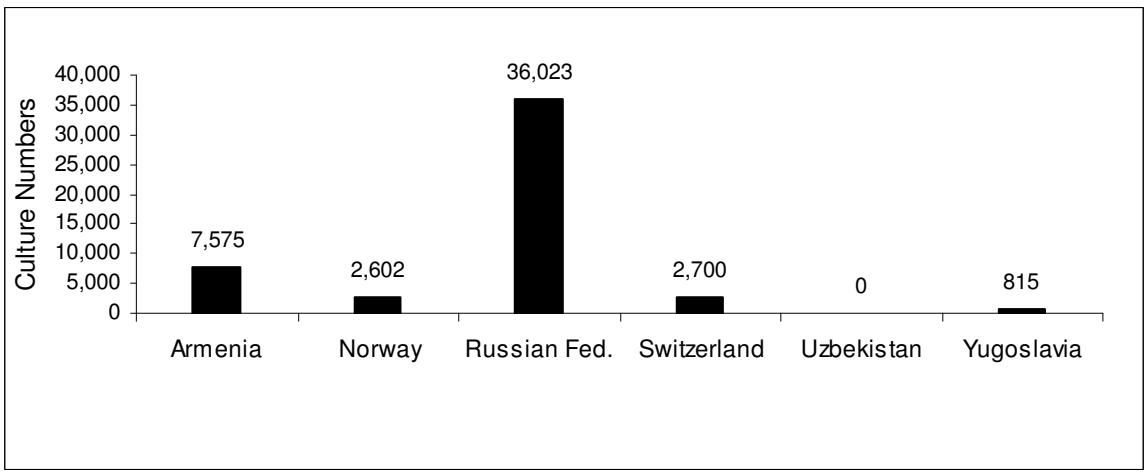
7. Culture Numbers in Asia



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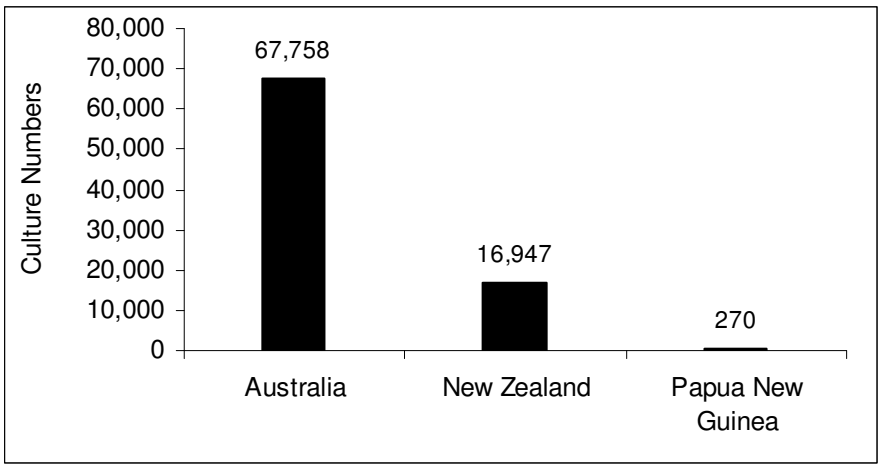
8. Culture Numbers in Other Eıropean Countries



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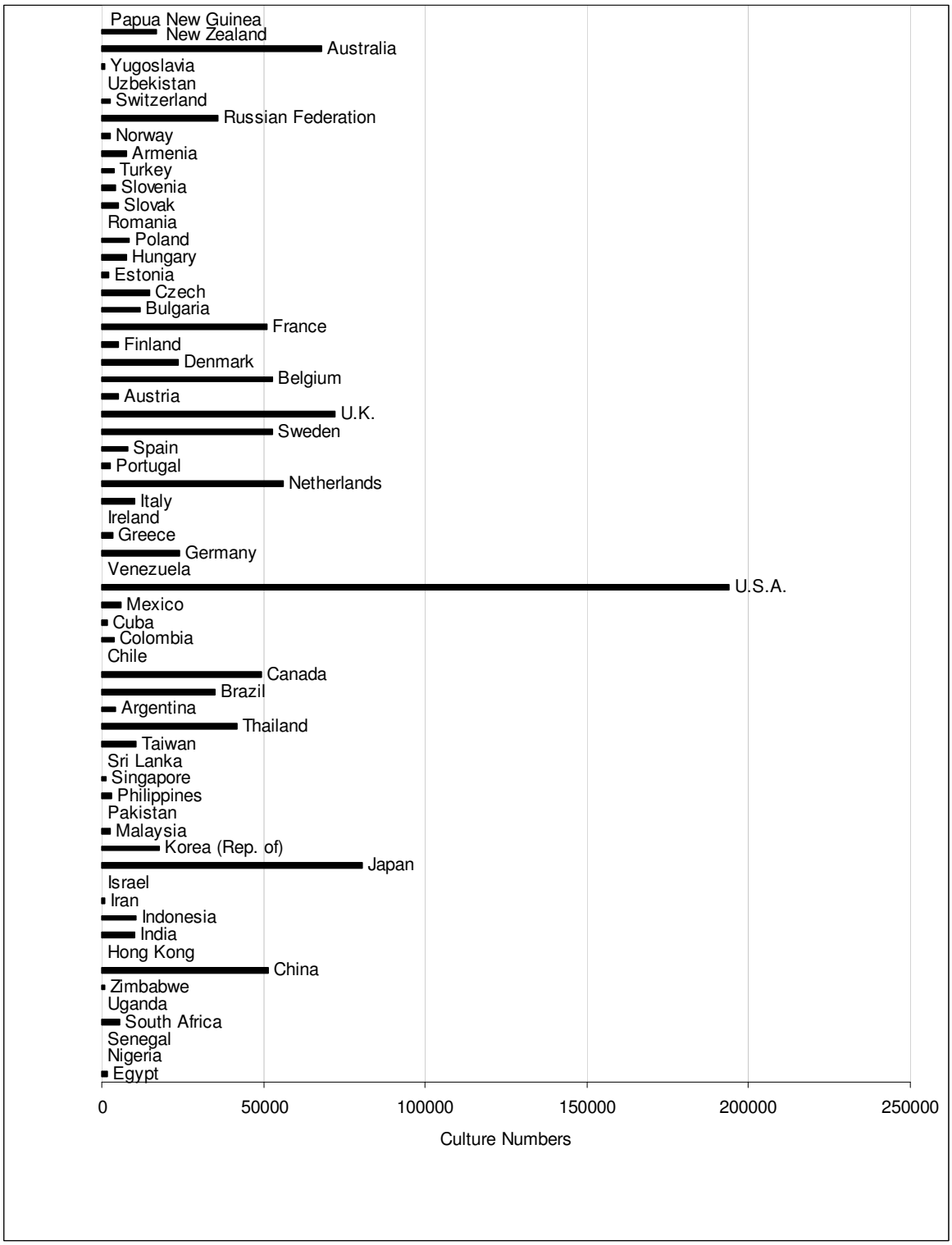
9. Culture Numbers in Ocenia



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10. Culture Numbers in All Registered Countries

ANNEX 5

USPC CLASSES ASSOCIATED WITH EACH BIOTECHNOLOGY FIELD

ANNEX 5

USPC CLASSES ASSOCIATED WITH EACH BIOTECHNOLOGY FIELD

Class	Label	Related Class in USPTO
1	**ANIMAL**	800/21-25, 800/3; 800/8-20
2	**PLANT**	47/57.6;
		435/410-431
		800/260-275; 800/276; 800/277; 800/278-294; 800/295-323.3
3	**MICROORGANISM**	435/235-239; 435/242; 435/243-261
		424/93.1-93.73
4	**BIOLOGICAL MATERIALS FOR THERAPEUTIC APPLICATION**	424/85.1-85.7; 424/94.1-94.67; 424/130.1-283.1; 424/520-583
		435/68.1
		514/2-22
5	**BIOLOGICAL MATERIALS WITH GENERIC APPLICATIONS**	435/174-182
		435/183-234
		530/300-345; 530/350-427; 530/800-868; 930
6	**TISSUE CULTURE**	435/1.1-1.3; 435/2; 435/325-408; 600/36
7	**GENETIC ENGINEERING**	536/22.1-25.2; 514/44; 536/25.1-25.2
		435/69.1-69.9; 435/320; 435/440-490
8	**BIOSYNTHESIS**	435/41-67; 435/68.1; 435/70.1-70.5; 435/71.1-71.3; 435/72-105; 435/106-116; 435/117-168; 435/169-171
		502/007
		800/4-7
9	**BIOSENSORS**	435/3; 435/4-40.52; 436/500-548; 436/800-829;
		536/25.3
10	**METHODS OF ANALYSIS (NON-BIOLOGICAL)**	205/777.5;
		356/39-40; 382/133-134; 436/63-67
11	**APPARATUS**	204/403;
		424/9.1-9.81
		435/283.1; 435/284.1; 435/285.1-285.3; 435/286.1-286.7; 435/287.1-288.7; 435/289.1-305.4; 435/306.1; 435/307.1; 435/308.1-309.4
12	**BIO-SEPARATION AND CLEANING**	210/600-602; 210/606; 210/610-611; 210/615; 210/632; 210/645; 435/262-282
		210/922; 510/114; 510/226; 510/300; 510/305; 510/306; 510/374; 510/394; 510/530; 510/FOR102; 510/FOR228
13	**FERTILIZERS & PESTICIDES**	71/6-10; 71/15-24
		504/117
14	**BIOINFORMATICS**	702/19; 702/21; 703/11-12, 702/20, 382/129

Source: Patel,Peri (2003). UK Performance in Biotechnology-related Innovation: An Analysis of Patent data. SPRU, Final Report Prepared for the Assessment Unit of the UK Department of Trade and Industry,University of Sussex

ANNEX 6

IPC CODES ASSOCIATED WITH EACH BIOTECHNOLOGY FIELD

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A 01 H 1/00	Medical Preparaions Containing Peptides
A 01 H 4/00	Plant reproduction by tissue culture techniques
A 61 K 38/00	Medicinal preparations containing peptides
A 61 K 39/00	Medicinal preparations containing antigens or antibodies
A 61 K 48/00	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
C 02 F 3/34	Biological treatment of water, waste water, or sewage characterised by the micro-organisms used
C 07 G 11/00	Antibiotics
C 07 G 13/00	Vitamins
C 07 G 15/00	Hormones
C 07 K 4/00	Peptides having up to 20 amino acids in an undefined or only partially defined sequence; Derivatives thereof
C 07 K 14/00	Peptides having more than 20 amino acids; Gastrins; Somatostatins; Melanotropins; Derivatives thereof
C 07 K 16/00	Immunoglobulins, e.g. monoclonal or polyclonal antibodies
C 07 K 17/00	Carrier-bound or immobilised peptides, Preparation thereof
C 07 K 19/00	Hybrid peptides
C 12 M	Apparatus for enzymology or mıcrobıology
C 12 N	Micro-organisms or enzymes; compositions thereof, propagating, preserving, or maintaining micro-organisms, mutation or genetic engineering; culture media
C 12 P	Fermentation or enzyme-using processes to synthesise a desired chemical compound or composition or to separate optıcal ısomers from a racemic mixture
C 12 Q	Measuring or testing processes involving enzymes or micro-organisms, compositions or test papers therefor; processes of preparing such compositions; condition-responsive control in microbiological or enzymological processes
C 12 S	Processes using enzymes or micro-organisms to liberate, separate or purify a pre-existing compound or composition; processes using enzymes or micro-organisms to treat textiles or to clean solid surfaces of materials
G 01 N 27/327	Biochemical electrodes
G 01 N 33/53	Immunoassay; Biospecific binding assay; Materials therefor (medicinal preparations containing antigens or antibodies
G 01 N 33/68	involving proteins, peptides or amino acids
G 01 N 33/74	involving hormones
G 01 N 33/76	Human chorionic gonadotropin
G 01 N 33/78	Thyroid gland hormones
G 01 N 33/88	involving prostaglandins
G 01 N 33/92	involving lipids, e.g. cholesterol