Norwegian University of Life Sciences
Department of International Environment
and Development Studies

Master Thesis 2015
30 credits

Trends in Intellectual Property Rights to Genetically Modified Agricultural Products

(exemplified by legislation of Ukraine)

Oleksandra Chornous

The Department of International Environment and Development Studies, Noragric, is the international gateway for the Norwegian University of Life Sciences (NMBU). Established in 1986, Noragric's contribution to international development lies in the interface between research, education (Bachelor, Master and PhD programmes) and assignments.

The Noragric Master thesis is the final thesis submitted by students in order to fulfil the requirements under the Noragric Master programme "International Environmental Studies", "Development Studies" and "International Relations".

achernous@yandex.ru

Noragric
Department of International Environment and Development Studies
P.O. Box 5003
N-1432 Ås
Norway
Tel.: +47 64 96 52 00
Fax: +47 64 96 52 01
Internet: http://www.nmbu.no/noragric

Declaration

I, Oleksandra Chornous, declare that this thesis is a result of my research investigations and findings. Sources of information other than my own have been acknowledged and a reference list has been appended.

This work has not been previously submitted to any other university for award of any type of academic degree.

Signature: ……..

Date: …….

A B S T R A C T

Genetically modified agricultural products (hereinafter-GMAPs) are produced based on genetic resources (hereinafter - GRs), which could be treated as valuable ecological (for functioning of the ecosystem) and economic (for social development) resources. They are identified as part of the environment and commercialized particles/processes of nature with implementation of the UN Convention on Biological Diversity, 1992 (hereinafter - CBD), and the Agreement on Trade Related Aspects of Intellectual Property Rights of the World Trade Organization, 1994 (hereinafter - TRIPS), respectively. The international community faces new challenges in establishing legal regimes for GMAPs, based on the principles of fairness, equality, ensuring of private property, and precautionary principle.

This thesis examines implementation of CBD and TRIPS (as regards IPRs to GMPs) in developing countries (Ukraine is taken as an example). The legal framework on IPRs to GMAPs in Ukraine is analyzed together with socio-economic factors that affect its efficiency. The thesis also investigates legal nature and social functions of patenting as one of the disputable types of IPRs to GMAPs. Finally, consideration is given to the potential of GR management at the national level.

Theoretical approach is combined with practical examples of genetic resource management. That combination helps to identify obstacles in the development of genetic resource management, analyze the effectiveness of the existing legal rules, and understand the trends in IPRs to GMAPs. Some recommendations to improve the legal regime of IPRs to GMAPs in Ukraine are formulated.

This master thesis employs the method of qualitative analysis, investigating the general issues on environmental and trade regimes of GRs, and the conditions of compliance of Ukraine with appropriate international and European requirements. Discourse analysis is used to identify points of view and issues which shape debates about IPRs to GMAPs. An interview clarifies the Russian legal perspective on GRs.

Key words: genetic resources, precautionary principle, intellectual property rights, patent.

A C K N O W L E D G M E N T S

I would like to take this opportunity to express my gratitude to everyone who supported me throughout the Master's program International Environmental Studies at the Norwegian University of Life Sciences.

First and foremost, I have to thank my research supervisor *Assoc.Professor Trygve Berg* for his aspiring guidance, brilliant comments and suggestions during writing thesis. He was very patient with my knowledge gaps in the area of biotechnology and invested his full effort in guiding me in achieving my goal. Without his assistance and dedicated involvement in the process, this paper could not be possible.

I would like to express my special appreciation and thanks to *Professor Yuri. S. Shemshuchenko* from V. M. Koretsky Institute of State and Law of the NAS of Ukraine, who introduced me to the International Environmental Law. I would like to thank him for encouraging my research and for allowing me to grow as a scientist in Ukraine. I express my warm thanks to *Professor Nataliya Malysheva* for her support and guidance. I have always carried positive memories of her classes in the university and the time of working side by side with her in the research institute.

Nikolai Kichigin, Leading Research Fellow of the Institute of Legislation and Comparative Law under the Government of the Russian Federation kindly assisted me with an interview. I am sincerely grateful to him for sharing his truthful and illuminating views on a number of issues related to the IPRs to GMAPs in the Russian Federation.

I would like to thank the staff from the Department of International Environment and Development Studies, *Noragric* at the Norwegian University of Life Sciences for their support and understanding over the past two years. A special gratitude I give to our Study Coordinator, *Ingunn Bohmann*, whose suggestions and encouragement helped me to organize my study process especially during thesis writing.

A special thanks to my family for all of the sacrifices that they have made to me. I would like to devote this thesis to the memory of my parents, who taught me to love life and be optimistic despite hardships. I would also like to thank all of my friends who supported me in writing, and inspired me to strive towards my goals.

T A B L E OF C O N T E N T S

Figures

LIST OF ABBREVIATIONS

GMAP	Genetically Modified Agricultural Product
ABS	Access-Benefit Sharing Agreement
CBD	UN Convention on Biological Diversity, 1992
CCU	Civil Code of Ukraine
CS	EU Common Strategy on Ukraine, 1999
ECU	Economic Code of Ukraine
EU	European Union
GMO	Genetically Modified Organisms
GMP	Genetically Modified Product
GR	Genetic Resource
IPR	Intellectual property right
NDUS	Novelty, Distinct, Uniform, and Stable
PBRs	Plant Breeder's Rights
PCA	Agreement for Partnership and Cooperation between the European Communities and their Member States, and Ukraine, 1994
PEBLDS	Pan-European Biological and Landscape Diversity Strategy, 1995
SPS Agreement	WTO Agreement on Sanitary and Phytosanitary Actions, 1994
SSPRPV	State Service for Protection of Rights to Plant Varieties of the Ministry of Agrarian Policy of Ukraine
SVPS	State Veterinarian and Phytosanitary Service (Derzhvetphytosluzhba) of Ukraine
TRIPS	WTO Agreement on Trade Related Aspects of Intellectual Property Rights, 1994
UPOV	International Union for the Protection of New Varieties of Plants
USSR	Union of Soviet Socialist Republics
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Chapter 1

INTRODUCTION

Well-supported science aids development of industry. Genetic engineering is considered a branch of science along with biology and chemistry. Development of genetic engineering has been stimulated with the adoption of TRIPS and establishment of IPRs to genetically modified products (hereinafter - GMPs). However, their introduction also created a conflict over GRs as common pool resources regulated by CBD. The conflict with establishment of CBD and TRIPS regimes could be described as a fight for ecological standards and competitiveness, which involve complex issues.

CBD \ the Cartagena Protocol on Biosafety to the Convention on Biological Diversity of May 15, 2000 (effective as of September 11, 2003; hereinafter – Cartagena Protocol) also established the precautionary principle. Investigation of its compatibility with trade regime of TRIPS demands employment of an ecosystem-based approach to identify environmental problems, which appear on all scales and levels: global, international, regional, national and local. In order to compare the applicability of CBD and TRIPS on two key levels - international and national, and identify peculiarities of implementation of international rules at the national level, Ukraine was selected as an example of a developing country ("The World Bank: Country and Lending Groups", no date (hereinafter - n.d.)). Legal regime of genetic engineering in Ukraine is evaluated in comparison with international legislation and national legislation of other countries (particularly, the Russian Federation). Though genetic engineering itself does not exploit natural resources, the access to and use of GRs is a source of conflict for stakeholders. Value of GRs depends on the functions performed by them for environment, people, and economy.

Based on definitions of terms, given in Art.2 of CBD, GRs may be defined as biological materials of actual or potential value, containing functional units of heredity. They are also identified as one of "three 'hierarchical categories' to which the 'diversity' label affixes: diversity of genes, diversity of species and diversity of ecosystems" (Linarelli J., 2004: 23). Finally, GRs are also recognized as "providers and holders of related traditional knowledge,

and frequently belong to developing countries rich in biodiversity" (European Parliament Report No. 2012/2135 (INI).

The concept of GRs is described differently in the national law. For instance, it has narrow and wide definitions in law of the Russian Federation. Firstly, the narrow definition of animal GRs was approved in the Federal Law "On the Animal World" of April 24, 1995 No.52-FZ: "Genetic resources of the animal world are the part of biological resources including genetic material of the animal origin containing the functional units of hereditary background" (Appendix 1: Interview with Nikolai Kichigin, 2014). This definition reflects Art.2 of CBD. Later the broader definition of 'genetically modified organisms' was stated in the Federal Law "On Government Control of Genetic Engineering" No.86-FZ of June 5, 1996: "This is an organism or few organisms, any noncellular, unicellular or multicellular organism able to reproduce and transfer essential genetic material different from natural organisms received through applying the methods of genetic engineering and containing genetic material including genes and their fragments and combinations of genes" (Appendix 1: Interview with Nikolai Kichigin, 2014). Legal definition of the object of human activity shows its role in definite society, and influences definition of appropriate legal regime and governance.

GRs are widely used in biotechnology that makes or modifies products or processes for specific use (Art. 2 of CBD). For example; food for people with special needs, drugs, cosmetics, high-yield plants. Such products and processes may make physical alterations to the environment and have benefits and drawbacks. Understanding of the benefits and drawbacks influences decision-making.

Decision-making in GR management has a moral aspect. Moral dimensions of issues on GRs create an ethical framework, as the basis of international policy on GRs. The policy declares environmental protection, protection of biodiversity, human health, and equality of nationalities, safety and availability of food.

Generally speaking, rational decision-making is hampered by lack of knowledge and time. At the core of individual rationality is a private interest. The individual rationality can be both dependant on organizational or institutional interests or influence them, making input into shaping/reshaping GR policy. The consequences of the policy affect the efficiency of the GMP's use.

A combination of institutions and agents are at work in GR management and influence the pecularities of governance structure. That is why, the theory of political and economic agents is employed in this thesis.

1.1. Problem statement

Objective of the Master's thesis is to identify the main discourses on IPRs to GMPs and their influence on the national GR policy. Special focus is on the patenting of GMAPs as of the most disputed type of IPRs. As an instrument of the national policy, legislation on IPRs to GMPs in Ukraine is evaluated within the context of the environmental requirements to GR management in Ukraine. National interests and economic and political conditions are taken into account too. The most important issues in genetic engineering are explored in light of the socio-economic development of Ukraine.

The core of the discussion is regulatory approach to patenting as the type of IPR's protection of GMAPs; correlation of trade and environmental aspects of the international/national policy in relation to the property rights to GMAPs.

Exploring IPRs to GMAPs, the author considers GRs as common-pool resources, GMPs as derivatives obtained from the GRs, and genetic processes as biological processes transmitting hereditary traits from one organism to another. The author distinguishes these two notions by looking at GRs in the environmental context, and at GMPs/GMAPs - in the context of private property. Thus, the term GMPs, including GMAPs, is used in this thesis to cover both GMPs and genetic processes.

The author focuses on the international and national (Ukrainian) legal rules on IPRs to GMAPs taking into account the influence of environmental regime on the patenting of GMAPs. Legal regulation of IPRs to GMAPs in Ukraine is characterized by use of inter-branch (environmental, civil and economic) legislation and inter-sector integration, which both affect a complexity of issues on IPRs to GMAPs and demands application of complex data analysis.

The aim of this thesis is to analyze the efficiency of implementation of the international agreements on the IPRs to GMPs in developing countries' law (Ukraine is taken as an example). In particular, provisions of CBD and TRIPS are analyzed and compared with the Ukrainian legislation in relation to IPRs to GMPs. For the achievement of such aim the legal framework on IPRs to GMAPs in Ukraine is reviewed together with the obstacles which affect its efficiency. Finally, the potential of GR management is evaluated at the national level.

The thesis is limited to the exploration and description of the Ukrainian legal regime of IPRs to GMAPs, and identification of the problems in application of GR management in Ukraine. Comparative analysis of international rules and general provisions of Ukrainian law is made in this thesis. Certain legal rules of Ukraine, such as the application of IPRs to GMAPs, rights and obligations, and responsibility of stakeholders, are explored in order to clarify peculiarities of the legal regulation of IPRs to GMAPs in Ukraine.

The legal regime of IPRs to GMAPs in Ukraine is explored through the prism of three aspects:

1. Legislative; which includes exploration of the Ukrainian legislation to identify priorities and tendencies in GR policy.
2. Institutional; which serves to identify the strength of administrative structure (a governmental authority at the national level) and evaluate its efficiency.
3. Financial; which helps to focus on evaluation of financial incentives for GR management development in Ukraine, particularly, to define and prioritize investment needs.

The following research questions are formulated:

1. How were international rules on patenting of GMAPs implemented in Ukraine?
2. How does the precautionary principle influence the implementation of international rules on IPRs to GMAPs at the national level?
3. What are the obstacles for the development of GMAP patenting in Ukraine?

The research questions help to identify the trends in IPRs to GMAPs, Ukraine being taken as an example of a developing country. GR management in Ukraine is evaluated mainly via legislative approach. In particular, evaluation of an ecosystem's potential includes evaluation of the GRs as of economic and ecological resources. As economic resources, they support

social development. As ecological resources, they are central to functioning of the ecosystem. In other words, GRs are explored both as part of the environment and commercialized particles of nature. So, proper GR management includes an integrated evaluation of the role of the environment and its ecosystems as of a source of natural capital, society's vital and spiritual strength, and of a receiver of life activity's byproducts.

From a constructivist perspective, GR management could be seen as a social construct where agents both influence and are influenced by the social structure. So, the concept of IPRs to GMAPs as a social phenomenon is also revealed. Influence of our perception as perception of agents and definition of the influence in the social context is considered. This constitutes a base for analysis and interpretation of the legal regime of the IPRs to GMAPs and should bring new perspectives into understanding of GR management.

The author's findings from the Ukrainian experience of implementing international law on the IPRs to GMAPs could give insight into the circumstances which are intrinsic to GR management. The experience of Ukraine could be applicable to the national policy of other developing countries.

1.2. Structure

This Master's thesis consists of eight main chapters. Firstly, general issues on environmental and trade regimes of GRs are reviewed, and a problem statement, the objective, the aim, and research questions of the thesis are identified.

Secondly, background information on international regulation of property rights to GRs and general provisions of Ukrainian law on the implementation and legal force of the international law are presented. The legal regime of GRs is described based on CBD and TRIPS. Furthermore, two different regimes at the international level – the regime of GRs as of common-pool resources, and the regime of GMPs (and genetic processes) as of patented property are analysed. Theoretically, the resulting institutional change should reduce conflict between stakeholders about access to and use of GRs. Harmonization of the present legal rules on IPRs to GMAPs via the World Patent System is argued to be vital.

Thirdly, the theoretical framework for the analysis of GRs's regime is described. In particular, the main aspects and link between institutional theory, risk and uncertainty are outlined. Fourthly, methods such as qualitative research, interview and discourse analysis are identified and characterized in order to cast light on the research process used to produce this Master's thesis.

The scope of Ukrainian legislation on GRs is briefly described in Chapter five. Academic discussion of trends in development of Ukrainian law on IPRs to GMAPs is presented. GR policy is evaluated via a combination of positive and normative perspectives. To understand how it works in practice, peculiarities of implementation of international law at the national level (Ukraine is taken as an example) are described through normative analysis. Further, positive analysis is used to evaluate the efficiency of legal regime of IPRs to GMAPs and to identify obstacles for development of genetic engineering in Ukraine. In order to carry out a complex analysis and evaluate efficiency of the regime, the integration approach (establishment of ecological requirements in all spheres of human activity and sectoral policy) is used, together with the ecosystem approach.

Chapter six casts light on the legal regime of GRs, their role for environment and society. Identification of the main criteria for definition of derivatives from GRs as of an object of IPRs, and of the circle of stakeholders in Ukraine helps to understand peculiarities of genetic engineering there. Furthermore, exploring legal mechanisms of IPRs to GMPs through description of the main rules on patenting, rights, obligations and responsibility of stakeholders reveals how interests of actors are protected by the Ukrainian law and portrays the efficiency of the Ukrainian policy on GR management.

Using discourse analysis, the author identifies viewpoints and issues which shape debates about IPRs to GMPs. In particular, the discussion of the main findings concludes that Ukraine has a well-established legal regime in the area, but its socio-economic policy creates obstacles for development of genetic engineering. Generally speaking, economic principles and social needs influence the articulation of national policy and its application in practice. Unfortunately, this rule does not apply in Ukraine. The conclusion contains answers to the research questions with evaluation of outcomes of the research and identification of trends.

Chapter 2

BACKGROUND

Traditional production on farms is based on free access to seeds/breeding animals, and their broad selection. In order to enrich the genetic pool, farmers have crossed different varieties. In fact, germplasm exchange began with the help of settlers and sailors a long time ago. It has had positive (like improvement of food supplies) and negative (for instance, the Irish potato famine caused by narrowing of the genetic base of food supply and monocropping) consequences (Carlson J.C., 1996; Cottier T., 1998; Kennedy R., 2006; Maguire J. Wai-Shing, 2012). Referring to issues of free-riding and breach of cooperative norms by colonizators, Sabrina Safrin (2007) identifies this case as "biocolonialism" (p. 1949). Also, European and American governments initiated programs to collect GRs and plants from around the world. As Jonathan C. Carlson (1996) mentioned: "…by the 1930s both Germany and the United States had begun to grant some intellectual property protection to biological inventions. By the 1980s, plant breeders had been granted significant intellectual property protection under national laws in industrialized countries…" (p. 99). At the same time, international policy on GRs has been pursued to rescue or maintain genetic diversity, and prevent genetic erosion.

Previously, plant GRs were identified in the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture (1983) as "a heritage of mankind to be preserved and to be freely available for use, for the benefit of present and future generations". Later FAO recognized the importance of reaching consensus on "sovereignty over PGR (plant GR-*O.Ch.*), access to breeders' and farmers' material and implementation of Farmers' Rights through an international fund" (Clause 103 of the Report of the Conference of FAO - Twenty-Sixth Session, 1991). From that moment, "the concept of mankind's heritage, as applied in the International Undertaking on Plant Genetic Resources, is subject to the sovereignty of the states over their plant genetic resources" (Preamble of the FAO Conference Resolution 3/91, 1991).

The CBD established the sovereign rights over biological resources, including GRs, with the aim of identifying the responsible stakeholder for conservation of GRs. In whole, sovereign rights are understood in the legal theory as external sovereignty ("legal independence from other states" (Kiss, A. & Shelton, D., 2007: 2)) and internal sovereignty ("exclusive jurisdiction over activities within their own territory" (Kiss, A. & Shelton, D., 2007: 2)). Alexandre Ch. Kiss and Dinah Shelton (2007) wrote: "The sovereignty of states has a determinative impact on the law-making process, by implying that state consent is needed both to create international legal obligations and to invoke procedures for the settlement of international disputes" (p. 2). The state consent is in accord with the national interest of the country.

CBD also provides for principles of access to GRs and benefit sharing. The intention is to reduce or prevent biopiracy. A definition of biopiracy was given in the Preamble of European Parliament Report No. 2012/2135 (INI) as: "the industrial practice of privatising and patenting the traditional knowledge or genetic resources of indigenous peoples, without obtaining authorisation from or providing compensation to source countries". Taking into account the above mentioned features, the CBD is identified as a framework convention, one of the main tasks whereof is to resolve the North-South conflict.

The legal regime of GRs was complicated by their identification as an information system. "Such information, genetically encoded, is either exclusively contained in nature, yet untouched by man, or it exists in combination with human knowledge as how to make good use of such information or know-how - with or without knowledge of the gene code. Appropriation of such information poses different problems from appropriation of physical matter. It is not specifically located and contained in matter, but may exist at many different places at the same time. It is ubiquitous" (Cottier T., 1998: 558-559). Thus, we can agree with James O. Odek (1994) that: "…the aggregate amount of a specific plant genetic resource possessed by a country is not the issue; rather, the issue is the distinct genetic information extracted from a country without compensation" (pp.156-157). Peculiarity of GRs is that it could be valued based on the minimal amount of resources, while tangible resources (like timber, oil) are valued based on the proportion of the extracted resources. Put another way, IPRs "relate to pieces of information that are or may be incorporated in tangible objects, but protection only covers the immaterial contents" (Correa C.M., 1996: 60). Arvind Subramanian (1992) specified: "…knowledge and information have the hallmarks of public

goods. The market failure arises because if knowledge becomes public, agents other than its creator can easily or costlessly appropriate the benefits arising from such knowledge" (p.106).

GR management needs data protection, which should be balanced with user's right to access the protected property (Baba, E.J., 2003; Colston C., 2007; Thomas, D. J. & Dhar, P., 2008). Agents began to use patenting as the mechanism to protect IPRs to GRs. As a result, IPRs to GMPs has been regulated by the TRIPS in Appendix 1C of the Marrakesh Agreement (or the World Trade Organization Agreement). It was negotiated under General Agreement on Tariffs and Trade (GATT), commonly referred to as the Uruguay Round (which extended from 1986 to 1994). Provisions of TRIPS apply to Members mandatorily and are subject to the World Trade Organization (hereinafter – WTO) dispute settlement mechanism. For the first time IPRs have been introduced with regard to the multilateral trading system through a set of comprehensive disciplines. It was a consequence of scientific discussions as well. So, important role of GRs in international competitiveness was underlined in Jack Kloppenburg's "First the Seed" (1988). Then commodification (or commercialization) of GRs turned into scientific concept (Cottier T., 1998; Linarelli J., 2004; Maguire J. Wai-Shing, 2012; Odek J.O., 1994; Venbrux G.K., 2006). Ownership and control of GRs has become 'a critical element of developing countries' trade policies" (Odek J.O., 1994: 144).

"Elinor Ostrom has analyzed three arguments for a "modified" private property model rather than an open-access "commons" regime. The first is Garrett Hardin's *Tragedy of the Commons*, which explains that a resource unaccompanied by a right of exclusion is ripe for overuse and depletion. The second is the prisoner's dilemma, which shows that decisions premised on maximizing short-term individual self-interest may be at odds with an individual or community's long-term benefits. The third is Mancur Olson's *The Logic of Collective Action*, which describes the prevalence of the "free rider" problem. This problem arises from a lack of incentive to create or maintain a collective good, resulting when access or benefit to the good is free. These three narratives depict private property as efficient and open access regimes as misconceived and wasteful" (Aoki K., 2009: 2288). Legal nature of private property on GRs is highly debatable question due to contradictions between nature of GRs and classical understanding of private property.

IPRs may have a negative influence on the implementation of the CBD. As James O. Odek (1994) wrote: "…a report by GRAIN (Genetic Resources Action International – *O.Ch.*) has

concluded that the Biodiversity Convention is extremely weak and even counter-productive in two respects. First, the door is opened for the patenting of genetic materials. Second, the Convention excludes a crucial part of the world's biodiversity, ex situ plant genetic resources held in gene-banks. This exclusion has raised questions regarding the legal status of ex situ plant genetic resources" (pp. 163-164). Particularly, the debates arise around the ownership of plant GRs and access to the national gene-banks (Colston C., 2002). Art. 16 of the CBD specifies the importance of stakeholder's cooperation in order to ensure that rights, established in CBD, "are supportive of and do not run counter to its objectives".

Taking into account above mentioned features of CBD and TRIPS, John Linarelli (2004) classified them into 'commons-oriented treaties' (CBD, International Treaty on Plant Genetic Resources for Food and Agriculture) and 'property-oriented treaties' (TRIPS) (p. 32). Their provisions should be implemented into the national law of country-parties. Depending on their national interests, environmental and trade regimes of the GRs may have different levels of implementation. As an example, Ukrainian law is explored in the given thesis taking into account its social, economic and ecological conditions.

Ukraine lies between Europe and Asia (particularly, the Russian Federation). It is rich in biodiversity and has infrastructure for genetic engineering, developed during the Soviet Union. Gross Domestic Product (hereinafter - GDP) per capita of Ukraine was estimated as $ 2138 in 2013 ("The World Bank: Ukraine", n.d.), compared to $ 2085 in 2012 ("Trading Economics: Ukraine", n.d.). The only country in Europe which has lower GDP per capita is Moldova ($ 1136). This is even less than Turkey ($ 8717) to put it in perspective.

The population of Ukraine is currently 45 million. Ukraine's Human Development Index for 2012 is 0.74. It is "in the high human development category - positioning the country at 78 out of 187 countries and territories. The rank is shared with the former Yugoslav Republic of Macedonia" (UNDP Human Development Report, 2013). At the same time, Corruption Perceptions Index of Ukraine, which indicates level of corruption in the country's public sector, is ranked as 144 out of 177. With such indicators Ukraine is close to Uganda ("Transparency International: Ukraine", n.d.). 'According to the Index of Ecological Stability, the World Economic Forum in Davos (2002) positioned Ukraine on the 137th place out of 142 countries' (National Environmental Policy of Ukraine, 2007: 16).

Ukraine, as a part of Europe geographically, is familiar with the provisions of the European Union (hereinafter – the EU) due to the export and import lines. There are huge markets for agricultural products from/into Ukraine: "If we compare Ukraine with the world regions, we could see that the volume of trade with Asian countries has risen to $6 b. The second by the volume of export is the EU market, which has increased four times since 2005. Europe is also the biggest market we imported products from (for $3.3 b.)… Trade with the countries of EC (Customs Union) has not advanced over past 7 years. Russia needs substantial provision, and imported them for $43 b. from other countries. It neglected our propositions and bought the Ukrainian products only for $3.7 b" (Sadova I., 2014). Furthermore, environmentally-friendly and safe products are preferred most of all in Ukraine. As contradiction to GR policy, organic farming is constantly developing for last ten years (see, e.g.: Semchik V.I. (2010); Lushpaev, S.O. (2011); State Program on Development of Ukrainian Village Until 2015 on ORGANIC, approved by the Order of the Cabinet of Ministers of Septemder 19, 2007 No.1158; Development Strategy of the Agricultural Sector Until 2020, approved by the Ordinance of the Cabinet of Ministers of Ukraine of October 17, 2013 No.806-p). Such trends in agricultural policy of Ukraine are based on the experience of the 50s in the USSR and "green revolution" of 60-70s in the world: "The members of the USSR grew more productive plant varieties, and got an expansion of the irrigation lands, and an intensified use of fertilizers, and pesticides. They also introduced new equipment, which eventually raised yields. Though the number of those starving has reduced according to FAO statistics, the amount of clean soil, water, and biodiversity has also decreased" (Verkhovets V., 2013).

Ukraine has enough environmental problems except genetic erosion, like technogenic violation of the environment caused by the radioactive pollution from the Chornobyl catastrophe. That is why environmental protection is highly valued in Ukraine: "The cohesion of every society is based upon and maintained by a value system. The system may demand respect for the human person, propriety, patriotism, cultural values, or a particular social order. The protection of such fundamental values is generally recognized as a common concern of the community and is ensured through law, especially constitutional law" (Kiss A.Ch.&Shelton D., 2007: 13).

In order to promote clean environment, safety of agricultural products, and economic development, in Ukraine were announced *the general principles of business practice* . They included; ensuring of environmental safety and maintenance of environmental balance across

the territory of Ukraine (what is the duty of the State *pari passu* with a preservation of the gene pool of the Ukrainian people, according to Art. 16 of the Constitution of Ukraine (1996), protection of domestic producers, ensuring economic diversity and equal protection of all economic entities by the state, freedom of entrepreneurship (within the limits set forth by the law), protection of consumer rights (Art. 5, 6 (1) of the Economic Code of Ukraine, 2003). Property entails responsibility and it shall not be used to the detriment of a person and of the society as a whole, according to Art. 13(3) of the Constitution of Ukraine (1996). Thus, the ensuring of environmental safety and innovative development are provided simultaneously in Ukraine.

To understand the tendency of legal regulation of IPRs to GMPs in Ukraine, one should also take into account the environment, where and how GMPs could be used/prohibited, and possibilities for the development of GR management in the country. The aim, when creating a new product, is to put it to practice. Otherwise, there are no stimuli to produce new products. That is why IPRs and the precautionary principle are linked in this case. Particularly, IPRs to GMPs has ethical issues related to medicine, life sciences and associated technologies, as applied to human beings, and is addressed by the Universal Declaration on Bioethics and Human Rights of October 19, 2005 (UNESCO, 2005).

Ukraine, which belonged to 30 intellectually elite countries, inherited from the USSR significant scientific and technical potential (Paragraph 4, Preamble of Recommendations of Parliamentary Hearings, 2007). As it is stated in the Recommendations of Parliamentary Hearings "National Innovative System of Ukraine: problems of formation and realization" (2007), nowadays Ukraine is still among the world leaders in the fields of fundamental sciences such as physics, chemistry, and medicine: "However, unlike the developed countries, where 85-90% of gross domestic product (hereinafter – GDP) is provided by means of manufacture and export of knowledge-based products, Ukrainian share of high technology market is 0.05-0.1 per cent while the whole market is estimated at $ 2.5-3 trillion" (Paragraph 6, Preamble of Recommendations of Parliamentary Hearings, 2007).

Application of the consumer-oriented approach in Ukraine results in the overexploitation of natural resources and an anthropogenic contamination. The present situation threatens human health and social development in the country. So, well-balanced environmental management

system is in great demand. Moreover, it is questionable which is less harmful – overexploitation of natural resources or genetic erosion?

Genetic engineering could be identified as an innovative activity, as it uses basic science to create new products, which improve the quality of lives of citizens. Such innovative activity is embedded into innovative system. The innovative system, regulated by the government, becomes a national innovative system. The dilemma of the national innovative system is that it does not reflect the national distinction of a specific country in most cases. The system reflects the world tendency in development. At the same time, it unites citizens in their desire to make scientific progress for their own country and to work in one direction in order to produce it. To be clear, the innovations are produced for the world market, but they can be unavailable on the local market. Genetic engineering should provide development of the three sectors (branches): science, education and knowledge-based industry. Successful implementation of this task would provide prosperity of country, as a leader in innovative production.

A common feature of the national innovative system is that its results work for the world, regardless of the nationalities or countries, which use innovations. At the same time, innovations are produced in the nationally established juridical order.

2.1. Legal background and general provisions of the Ukrainian law

Ukraine was affiliated with the Union of Soviet Socialist Republics 70 years. As a former republic of the USSR, it still has the status of a Charter Member of the United Nations since 1945. It acts as an independent subject of international law. As a result: "Thanks to this, prior to the 1990s, the Ukrainian S.S.R. participated in 18 multilateral international agreements in the field of environmental protection" (National Environmental Policy of Ukraine, 2007: 74).

Ukraine declared independence on August 24, 1991 (Declaration of Independence of Ukraine, 1991). Law of Ukraine "On Legal Succession of Ukraine" was approved on September 12, 1991. According to Art. 7 of this Law: "Ukraine is a successor of the rights and obligations resulted from the international agreements, concluded by the Soviet Union, and which do not

contradict to the Constitution of Ukraine and the interests of the state". Later Ukraine got membership in the Council of Europe on November 9, 1995 ("Council of Europe: Ukraine – Member State", n.d.). Trying to integrate with international, political and economic institutions, Ukraine began to europeanize its legal system.

Legal regulation of IPRs to GMAPs in Ukraine is complex. It reflects, first of all, a fundamental right to the adequate conditions of life in the environment of a quality that permits a life of dignity and well-being, and right to access environmental information, food safety and other human rights. Patenting of GMPs in Ukraine could be done taking into account necessity to provide environmental safety.

Ukraine has signed the major international agreements, which provided greening of agricultural production and limitation of GMO use. The list of international agreements ratified by Ukraine is long in view of the complexity of GR management and variety of natural resources involved in it. For instance, it includes environmental treaties, listed in Appendix 2. Specialized legislation on IPRs, ratified by Ukraine, consists of the international legal rules, listed in Appendix 3. These legal acts could be classified as soft laws (for instance, TRIPS) or hard laws (for example, CBD). In whole, "Ukraine has joined more than 20 multilateral conventions of an ecological orientation" and is a party "to about 50 multilateral international agreements on environmental protection. The issue of participation in more is to be decided. Besides United Nations multilateral international conventions, a significant layer of international agreements in which Ukraine is a participant were concluded during the last decade on a bilateral or regional basis. Thus, during the years of independence, about 40 bilateral international agreements on cooperation in the field of environmental protection were concluded on an intergovernmental or interagent level" (National Environmental Policy of Ukraine, 2007: 74-75). However, the quantity of signed international treaties does not necessarily mean quality of their implementation.

Application of GMAP's in Ukraine is carried out in accordance with the provisions of international law. In particular, rule of international law provision's priority over national law is one of the main rules in legislative system of Ukraine. Art.19 of the Law of Ukraine "On International Treaties" of June 29, 2004 and Art. 10(2) of the Civil Code of Ukraine of January 16, 2003 (hereinafter - CCU) amplified Art. 9 of the Constitution of Ukraine (1996) in that international treaties approved by the Verkhovna Rada of Ukraine (hereinafter - the

Parliament) as mandatory, shall be a part of the national legislation of Ukraine. They apply in the manner provided for in the national legislation. If an international treaty, which entered into force in due course, specifies any rules other than those contained in the relevant legislation of Ukraine, then the rules of the international treaty should be applied. According to part 2 Art. 9 of the Constitution of Ukraine (1996), "the conclusion of international treaties that contravene the Constitution of Ukraine is possible only after introducing respective amendments to the Constitution of Ukraine".

Regarding the IPRs cases, the Superior Economic Court of Ukraine gave the following interpretation: "Commercial Court shall take into consideration that the provisions of the international treaties in the field of intellectual property ratified by the Parliament of Ukraine as a part of the national laws, are the standards of direct legal effect and can be used in settlement of disputes independently and together with other norms of the national laws depending on the circumstances of the case" (Clause 1.2. of Resolution of the Plenary Session of the Superior Economic Court of Ukraine of October 17, 2012).

Thus, stakeholders may use provisions of the international treaties, signed by Ukraine, as norms of direct legal effect in Ukraine. The list of the main laws of Ukraine pertaining to IPRs to GMPs is given in Appendix 4.

2.2. Precautionary principle in Ukrainian legislation

Application of GMPs influences the quality of a range of natural resources (soil, water, biodiversity) and is typical of modern agriculture (except for organic farming). To analyze legislation on GR management, one should use an ecosystem-based approach and analyze legal regulation of sustainable use and conservation of natural resources, involved in GMPs application chain. Unfortunately, genetic engineering and application of its results could cause deterioration of biological and landscape diversity. Moreover, as Alexandre Ch. Kiss and Dinah Shelton (2007) mentioned: "It is, thus, up to each state, subject to its treaty and customary obligations, to determine the level of environmental protection it aims to achieve" (p. 12).

To avoid harmful impact on the environment and human health, there has been established the precautionary principle in law. It influences applicability of genetic engineering results in the field, too. To a certain degree, it helps to support sustainability of the ecosystem and avoid negative environmental influences on human health. Application of the precautionary principle is linked to some degree with the right to access environmental information. Therefore, it was mentioned in the "National Environmental Policy of Ukraine: Assessment and Development Strategy" (2007) that: "The obtained information should be suitable for explaining management decisions, as well as for informing the population" (p. 17).

Precautionary principle is established at the international level by the CBD, the Cartagena Protocol and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter - SPS Agreement), approved on April 15, 1994 *(*entered into force on January 1, 1995). It addresses the obligation of the GMP's producer to ensure safety of GMPs for people (particularly, for their health) and the environment.

John Linarelly (2004) underlined 'three decision procedures' used to explore the issue of the precautionary principle: "An economist might well accept substantial degradation of biodiversity if the sum of benefits from such degradation exceeds its costs. A utilitarian would take a similar approach. A deontologist cannot accept breaches of moral duties unless there is some rule that permits derogation, but a deontologist would be hard pressed to allow any substantial biodiversity degradation. A virtuous person would ask whether biodiversity preservation (or degradation) furthers a virtue such as justice or prudence" (p. 25). Since Ukraine got representetives from all these groups in decision-making, it is interesting to analyze how they keep balance of interests at the international and national levels.

Analyzing the complex relationships between competing interests, which are presented in 'the debate within the EU about the right to use various additives in food and regulation in the field of genetically modified organisms (hereinafter - GMO)', Arild Vatn (2005) wrote: "On the one side we have the interests involved in setting up a regime advancing unconstrained competition and on the other we have the interests involved in avoiding (future) harm. In general there seems to be great conflict between the interests of giving priority to competition on the one hand and to installing rules like the precautionary principle on the other" (p. 271). Developing his idea, uncertainty issue could be taken into account, too. In particular, in the case of balancing supply and demand, "firms are faced with problem of determining future

prices and quantity demands" (Vatn A., 2005: 188). This influences the willingness of GMP's producers to invest capital in research and production. Logically, if private property law is imposed on GRs (TRIPS regime), producers have incentives to develop this field." (to understand difference between CBD and TRIPS see: Appendix 5).

Since consumers and political agents influence and are responsible for the condition of the environment, the issue about the precautionary principle and uncertainty could be analyzed from their sides, too. In particular, Alexandre Ch. Kiss and Dinah Shelton (2007) mentioned: "…most environmental harm is caused by private sector activities and not those of governments. The ability of international law to regulate non-state conduct is, thus, essential to achieving effective environmental protection." (p. 2).

"The EU issued around 17 legal documents (directives, regulations, decisions) in the field of chemical substances and GMOs, according to the Handbook on the implementation of EC environment legislation (December 2003)" (National Environmental Policy of Ukraine, 2007: 54). The precautionary principle is also mentioned among *10 Strategic principles*, established in the Executive summary of the Pan-European Biological and Landscape Diversity Strategy (1995) (hereinafter - PEBLDS): "…careful decision making, avoidance, precaution, translocation, ecological compensation, ecological integrity, restoration and (re)creation, best available technology and best environmental practice, polluter pays, public participation/public access to information". The principles should be applied in order to achieve a wise management of biological and landscape diversity through all sectors using natural resources.

Most of the above mentioned principles are established in the national legislation of Ukraine. Particularly, they were specificated in the Constitution of Ukraine (1996) and Law of Ukraine "On Environmental Protection" of June 25, 1991 No.1264-XII (hereinafter - Law of Ukraine "On Environmental Protection", 1991). In pursuance of the recommendations of PEBLDS, the National Programme for Establishment of the National Ecological Network in Ukraine for 2000-2015 has been approved by Law of Ukraine of September 21, 2000 (hereinafter - the National Program of Ecological Network, 2000).

Analyzing provisions of PEBLDS in light of the current condition of the natural landscape in Ukraine, it becomes clear that they only partially meet the criteria to relegate them to the Pan-

European Ecological Network: "For example, the land fund's agricultural cultivation at the beginning of 2005 reached 72 percent of the country's territory, with 56 percent under plough… The area of the eroded lands is estimated at 49 percent of the agricultural land fund … Ukraine is characterized by a large number of depressed and ecologically degraded territories. Among these are irradiated areas in the Kiev and Kirovograd regions and elsewhere, inundated lands, landslide and flood areas" (National Environmental Policy of Ukraine, 2007: 8, 15). Among the tasks on the protection and restoration of land resources, Clause 3 of the Program of Ecological Network (2000) includes the following:

- Optimization of agricultural lands and reduction of the degree of their tillage,
- Improvement of the structure of agricultural lands and their enrichment with natural components,
- Introduction of conservation cropping system with a contour meliorative organization of the territory,
- Limitation of the devastating heavy (intensive) use of the environmentally sensitive lands.

On the one hand, the National Program of Ecological Network (2000) should encourage use of GM seeds that would reduce tillage and increase harvest. On the other hand, this Program encourages conservation and sustainable use of natural resources in Ukraine.

Fulfillment of the precautionary principle by agricultural stakeholders is overseen by the State Agricultural Inspection of Ukraine. In accordance with its assigned duties, the Inspection performs such functions as "keeping measures of biological and genetic safety regarding agricultural plants upon creating, researching and practical use of genetically modified organisms in the open systems." (Clause 4 (e) of Provisions on the State Inspection of Agriculture of Ukraine of April 13, 2011).

The link between patenting and precautionary principle is seen in the License Provisions for Pursuit of Economic Activity on Trade by Pedigree (Genetic) Resources, Execution of Genetic Examination for Origin and Abnormalities of Animals, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine on October 1, 2012 (hereinafter – License Provisions, 2012). Clause 1.2 of License Provisions (2012) states: "The certificate (for licensing – *O.Ch.*) is aimed to: acknowledge the genetic resources as pedigree; confirm the quality signs of pedigree (genetic) resources claimed by their owner; execution of control for

authenticity of the origin and detection of the genetic abnormalities of the animals; the protection of the rights of consumers; control of genetic safety of the animals". Therefore, genetic expert examination of the origin abnormalities of pedigree animals should be executed. As prescribed by Clause 1.4. of Instructions for Conducting Examination of Livestock Breeding by DNA-markers of June 6, 2004, the expert examination includes: 1)immunogenotypic research; 2)cytogenetic research (regulated by the Instructions of Execution of Cytogenetic Control for Livestock Breeding, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine on June 1, 2004); 3)examination by DNA-markers (regulated by the Instructions for Conducting Examination of Livestock Breeding by DNA-markers, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine on June 6, 2004).

The link between patenting and precautionary principle could also be seen in the legislation of the Russian Federation: "According to Art. 11 of the Law "On Government Control of Genetic Engineering" of June 5, 1996 No.86-FZ, the products (services) received via use of methods of genetic engineering have to comply with obligatory requirements for environmental protection and pharmacopoeia items, as well as sanitary-epidemiological requirements and other requirements of the legislation of the Russian Federation. With respect to the genetically modified products which are subject to mandatory certification and conformity declaration, the certificate of conformity is issued or the declaration of conformity has to be approved in accordance with the established legislation of the Russian Federation on technical regulations" (Appendix 1: Interview with Nikolai Kichigin, 2014).

So, patenting of the new GMP does not mean that the GMP could be allowed for trade in Ukraine. For instance, the owner of the animal pedigree should go through the state regulated procedure to prove the environmental safety of the pedigree. Only after that may one carry out economic activity with the GMPs.

Complex approach to the IPRs to GMPs and the precautionary principle are established also in Clause 212.1 of the Decree of the President of Ukraine "The National Action Plan for 2013 in Respect of the Implementation of Economic Reforms for 2010-2014 years "On Rich Society, Competitive Economy, and Effective State" of March 3, 2013 (hereinafter - Decree "On Rich Society, Competitive Economy, and Effective State", 2013). It determines that the legislation about national biosafety system during the creation, test, transport and use of GM

organisms regulates the protection of authorship and related rights to the registered biotechnological plant varieties. The Decree states that application of biotechnology (including control, registration and turnover of GM seeds) should be accomplished in accordance with the requirements of the WTO and the EU.

Thus, to better understand the complex approach to the IPRs to GMPs and the precautionary principle, it is important to take into account WTO's and the EU's GR policy and its influence on the national policy of Ukraine.

2.3. The World Trade Organization, the European Union, and Ukraine

The development of economic, social, and environmental dimensions of agricultural production covers a range of issues related to the production, commodity circulation, environment protection and health of consumers. Legal regulation of farming should promote free trade and prevent the creation of barriers and restrictions to trade.

Development of market relations in Ukraine and its participation in international trade led to the affiliation of Ukraine in the WTO in 2008 (Ukraine ratified the Protocol of Accession to the WTO on April 10, 2008), prior to the affiliation of the Russian Federation in August 22, 2012 (See Appendix 1). In this regard, compliance of domestic products with the international standards of agricultural product's quality and safety, the greening of agricultural production became disputable issues in Ukraine. The long-term goal of agricultural production is sustainable development, as a fundamental principle, which was fixed in the Marrakesh Agreement Establishing the World Trade Organization of April 15, 1994 and the Doha Declaration on the TRIPS Agreement and Public Health of November 14, 2001.

In accordance with Appendix 1C of TRIPS, Member-states aim to ensure:

1) easy international trade through reduction of distortions and impediments;
2) effective and adequate protection of IPRs;
3) absence of barriers to legitimate trade in the form of measures and procedures to enforce IPRs.

Above mentioned international treaties, as well as others, guide the development of genetic engineering in Ukraine.

Agrarian and land reforms in Ukraine have been intensified with signature of *the Agreement for Partnership and Cooperation between the European Communities and their Member States, and Ukraine of June 14, 1994* (came into force on March 1, 1998; hereinafter - Partnership and Cooperation Agreement, PCA). It supposed to forward an integration process of Ukraine in the EU. According to Roman Petrov (2003), "the similar PCA were signed with Armenia, Azerbaijan, Belarus (did not enter into force), Georgia, Kazakhastan, Kyrgystan, Russia, Uzbekistan, Turkmenistan (has not entered into force yet)" (p. 2). In purcuance of PCA, Ukraine adopted a number of the legislative acts, which are listed in Appendix 6.

"This voluntary harmonization of Ukrainian laws to EU laws has engendered all major legal reforms undertaken by the Ukrainian government since the entering into force of the PCA. However, the scope of EU legislation to be approximated by Ukraine remains diverse. It comprises general principles of international law, selected provisions of the WTO legislation, and priority areas of law specified in the PCA and the CS" (the European Council Common Strategy 1999//CFSP on Ukraine of December 10-11, 1999, Helsinki – *O.Ch.;* Petrov R., 2003: 15-16*)*. In this context, it should be mentioned that the EU law differs from the international law. Yuriy S. Shemshuchenko (2005) wrote: "The main difference is that international law is not legally binding on states. For example, in Ukraine only international treaties ratified by the Parliament of Ukraine become a part of the domestic law. With regard to the law of the European Union, its directives are binding on the Member States that take precedence over national law" (p. 101). Since Ukraine is not a member of the EU, the EU Law does not have binding force for it. In pursuance of PCA, Ukraine should adapt its national law. This process was defined as 'voluntary harmonization' by A.Evans (1997) and 'autonomous adaptation' by Müller-Graff (1996) (Petrov R., 2003: 15-16).

Adaptation of legislation of Ukraine to EU requirements is a part of the process of integration into the EU. The purpose of adaptation is to achieve compliance of the Ukrainian legal system with the requirements that apply to countries intending to join the EU. It was clarified in the Preamble of Law of Ukraine "On the National Programme of Adaptation of Ukrainian Legislation in Compliance with the European Union" of March 18, 2004 that: "The objective of the adaptation of Ukrainian laws to the laws of the European Union is the achievement of

correspondence of the Ukrainian legal system *acquis communautaire* considering criteria presented by the European Union to the states intending to join the Union". In order to fulfil this task, Ukraine should provide effective law-making and enforcement, first of all, through establishment of the relevant institutions.

The associate membership in the EU, including the free trade regime, demands taking into account provisions of the EU directives and particularly requirements to agricultural products. As Sergey Bugera (2012) pointed out: "at least 80% of the European laws is applied in the Ukrainian national legislation" (p. 130). At the same time, the mechanism of adaptation of Ukrainian law to the legal rules of the EU was questioned for many years. Writing a research paper on the subject of integration of Ukraine into the EU, Roman Petrov (2003) made a logical conclusion: "None of the EU institutions have been explicit in defining the scope of EU legislation that could be considered a pattern for approximation. Neither the PCA nor the CS refer to the *acquis communautaire*, and in particular, to EC general principles that constitute the core of EU legislation. Similarly, neither the PCA nor other EU legal sources clearly specify what has to be done by Ukraine to activate the evolutionary clause and, consequently, to establish a free trade area with the EC. As a result, the national legislature found itself in quite a peculiar situation when it had to choose either between the blind reception of the whole *acquis communautaire*, or the consecutive approximation of Ukrainian laws to EU primary and secondary legislation as defined by the PCA and the CS priority areas" (p. 16).

Many government authorities, institutions and other legal entities have been involved with implementation of the national programs on the adaptation of Ukrainian legislation to the EU's legislation. For example, in order to coordinate the activities of public authorities on the adaptation of legislation and fulfil the integration strategy of Ukraine into the EU and other international institutions, *two advisory bodies* were created:

- *the National Council on adaptation of the Ukrainian legislation to the EU legislation under the President of Ukraine,* according to the Decree of the President of Ukraine of August 30, 2000 No.1033;
- *the State Council on European and Euro-Atlantic integration of Ukraine,* according to the Decree of the President of Ukraine of August 30, 2002 No.791.

They guide the executive agencies in the implementation of the integration programme, issue the non-binding proposals and identify the coherence and effectiveness of the adaptation

process. The watchdog role in coordinating and monitoring the speed of the integration process is given to *the Commissioner on the issues of European Integration* (Edict of the President of Ukraine of November 26, 2001 No. 146/2001).

The institutions established under the framework of the PCA (the Cooperation Council, the Cooperation Committee, and the Parliamentary Cooperation Committees) do not issue binding decisions for Ukraine. PCA establishes a political dialogue between Ukraine and the EC/Member States. It aims for development of economic relations and support of legal reforms in Ukraine. All politically important issues were resolved on the summits by the President of Ukraine and the President of the EU Council/the President of the Commission. Overall, the institutions established under the PCA framework do not play a significant role in the integration process. They have functions to monitor, give advice and coordinate the adaptation process in Ukraine.

The fields which require adaptation of laws and/or regulations of the EU by Ukraine have already been identified. They include: Intellectual property; Health and life protection of people, animals and plants; Environment; Protection of consumers; Technical rules and standards (Art. 51 of the PCA; Chapter V of the Law of Ukraine "On National Programme of Adaptation of Ukrainian Legislation in Compliance with European Union", 2004). So, no privileges for genetic engineering development over environmental rights and environmental safety could be seen in this case. The objective of the cooperation in the field of Agriculture and Agro-industry is identified as"…an implementation of the agrarian reform, a modernization, a reconstruction, and a privatization of agriculture, agricultural segment, and segment of services in Ukraine, the development of home and foreign markets for Ukrainian foods in the conditions of environmental protection considering the necessity of strengthening the food supply's security. The Parties will also aim at gradual approximation of Ukrainian standards to technical rules of Cooperation in industrial and agricultural food products including sanitary and phytosanitary standards" (Art. 60 of the PCA).

Moreover, considering a new geopolitical situation, caused by Ukraine's becoming a neighbor to the EU, the Strategy of Integration of Ukraine approved by the Presidential Decree of Ukraine "On Confirmation of Strategy of Integration of Ukraine into European Union" of June 11, 1998 (hereinafter - the Strategy of Integration of Ukraine, 1998) points out on the necessity "to define clear and thorough strategy of foreign policy as to the integration of

Ukraine into the European political (including foreign and security policy), informative, economic and legal space". Further, Paragraph 8 of the Strategy of Integration of Ukraine (1998) established that Sectoral Cooperation shall be focused on a research branch, industrial and agricultural cooperation. In particular, the Preamble of the Letter of the President of Ukraine to the Parliament of Ukraine "European Choice. Conceptual Foundations of Strategy of Economic and Social Development of Ukraine for 2002-2011 years" of April 30, 2002 underlined that "Ukraine belongs to the states with great scientific potential. First of all these are science schools recognized by the world, significant and often unique achievements in many fields such as engineering of new materials, and biotechnology…".

At the same time, a *priority of cooperation on environmental protection* is also underlined among the goals for cooperation in 28 fields. Art. 63 (2) of PCA states that, 'cooperation is aimed at combating the deterioration of the environment' and in particular regarding the following issue: the environmental impact of agriculture, soil erosion, and chemical pollution. Paragraph 9 of the Strategy of Integration of Ukraine (1998) determines: "An environmental protection is an acknowledged priority of the public policy and an object of increased attention of the society in the European countries, one of the major lines of the EU's activity and urgent problem for Ukraine caused not only by the consequences of the accident at Chernobyl Nuclear Power Plant but also by the environmental conditions in Ukraine." Overall, the cooperation on environmental issues serves *to create all-European safe and favorable environment*. An identification of priorities in the national politics helps to understand tendency in the economic and social development of a country.

GMPs have potential to bring economic benefits to developing countries. Specifically, they can make a significant input to the state budget. Protection of the environment can be successful if socio-economic factors are taken into account, too. The GR management and application of IPRs to GMPs should not be blocked by the precautionary principle. Ukraine has a special set of the legal rules on patenting GMPs, which will be analyzed later in this thesis.

Chapter 3

THEORETICAL FRAMEWORK

3.1. Institutional theory

Technological changes in biotechnology lead to emergence of new problems and trigger institutional changes. Institutions are constituted by agents (states and international organizations) who have power to undertake change. They sign international treaties in order to regulate conflicting interests (for example, TRIPS on the patenting issue) and establish institutional settings. Institutional changes are influenced by social ideas: "Because institutions are embodiments of social ideas or knowledge (Boland 1979; Hayek 1960; Nelson and Sampat 2001), institutional change is essentially a process of codifying ideas into institutions. Hence, we are intentionally designing an institution whenever we try to turn our social knowledge into institutions, even if our design is imperfect and done within bounded rationality due to the incompleteness of our knowledge" (Tang S., 2011: 18).

Institutional changes ensure availability of new technologies. New technologies demand investment and bring benefits. In relation to this, Arild Vatn (2005) wrote: "This is a necessary change if one wants private firms to be able to make profits from the new technology, which otherwise may be copied by others for free. Finally, new technology may also result in the loss of some income or benefit streams, a situation which may be opposed by the groups that are hurt. Agricultural policy in modern western countries can be understood as a response to such losses" (p. 179).

Society establishes institutions in biotechnology both for protection of interests and to influence agents with interest in GRs. Making choices on mechanisms of IPRs to GMPs and strategy of behaviour could be facilitated by categorization of institutions. Thus, the author focuses on the trade regime of GMAPs, which includes IPRs as a modern institution overlaped by the environmental regime of GRs.

IPRs to GMAPs are described from the perspective of designed institutional change where open access to GRs has been overlapped by the private property's regime. The theory of institutional change and governance theory are used simultaneously. Theoretical implications of institutional change are related to the process of establishing ownership of GRs, as a social phenomenon, which is ensured by law. In turn, IPRs to GMAPs is examined as social phenomenon, constructed into institutions through legal rules.

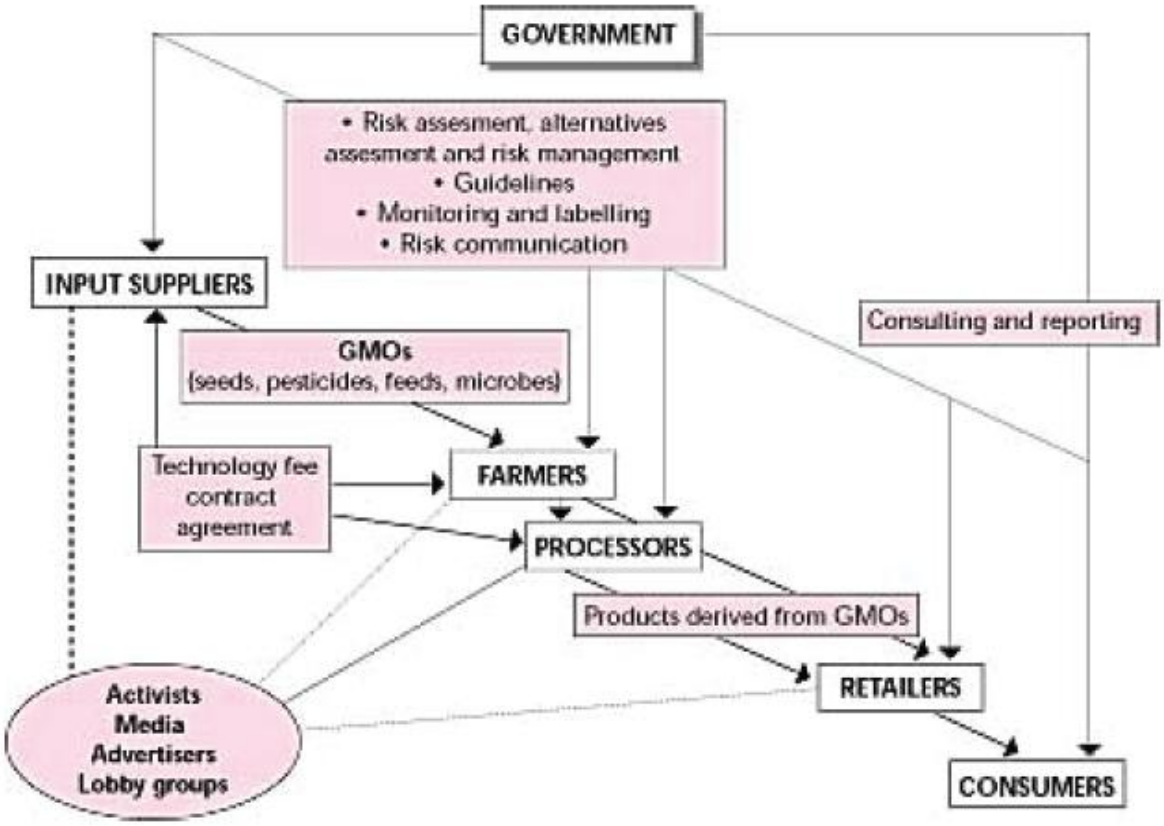
Established institutions build up a comprehension of issues and influence on the choice about suitable approaches. The importance of the theory of choice is underlined in describing the way in which Ukraine opts to implement international law on IPRs to GMAPs. In particular, Ukraine adopted *sui generis* as the most appropriate way for implementation of the international rules while ensuring national interests. Using the domestic-international dimension in the research aids answering the research questions and understanding the institutional structure of IPRs to GMAPs.

The peculiarities of food chain with GMPs identifies the roles of stakeholders in GR management: agents which have political power (government, activists, lobby groups); and agents which have economic power (farmers, processors, retailers, and consumers) (see Figure 1 on page 27).

The state's role in establishing a suitable institutional structure is examined through the distribution of GRs on market/public allotment, and allocation of costs for their use. Understanding of income and costs, and of the circle of agents clarifies the institutional setting in GRs managment.

One of the issues, which exists at the level of political agents, is the North-South conflict. It involves developed and developing countries. Norah Olembo shortly described this conflict: "So what went out free, would return with a price tag" (CGIAR, 1994). This could be explained by the Lockean labor theory of property which underlines role of labour in assigning value to the goods (Locke J., 1689). The added value endows property rights on the object (Odek J.O., 1994; Subramanian A., 1992). Similar point of view was held by the U.S. Supreme Court in *Diamond v. Chakrabarty* (1980): "[T]he organism constituted patentable subject matter because human intervention was a necessary step, signifying that the bacterium did not occur naturally" (Maguire J. Wai-Shing, 2012: 59-60). As a result, the case allows

patenting of micro-organisms in the USA. Alternatively, the Supreme Court of Canada made a determination in case *Harvard College v Canada (Commissioner of Patents)* (2002) that higher life form (oncomouse) is not patentable because: "…it is not a "manufacture" or "composition of matter" within the meaning of "invention" in s.2 of the Patent Act" (*Harvard College v Canada, 2002*). Opponents argue: "[P]lant genetic resources from developing countries are not simple products of nature. Generations have expended labor in improving these plant genetic resources. Locke's theory does not preclude proprietary rights to those resources because there is no minimum quantum of labour required to acquire proprietary rights" (Odek J.O., 1994: 154). In other words, collective labour's role in GR management should be considered, too.



Adapted from Economic Impacts of Genetically Modified Foods on the Agriculture Sector: A Synthesis (FAO 2001: 4)

Figure 1: Pictorial depiction of the food chain showing stakeholders and their roles

Another issue which exists at the level of political agents is related to the policy failure in developing countries (countries-origins of GRs). They need to improve organization of state administration, to reinforce democratic control and eliminate corruption. Otherwise, problems with making decision about getting access to GRs or getting compensation, as implementation of benefit-sharing principle, will stay the same, even if developed countries fulfill their obligations and responsibilities, according to the CBD. Policy failure in developing countries creates obstacles for implementation of trade regime of TRIPS on the national level. As an example, the author explored the legal regime of GRs in Ukraine.

Agents' interaction influences the construction of governance system. Likewise, knowledge about GRs influences the choice of agents. Such choice of agents influences what is perceived as rational behaviour. Herewith, an evalation of agent's capacity to coordinate behaviour should be taken into account, too. Arild Vatn (2005) clearly explained such situation in the following way: "A system may fit the dynamics of the resource well, but may still be undermined if the involved agents are motivated to break the rules and so on. This is a question about the general legitimacy of the regime and social coherence of the group involved" (p. 285).

Political and economic agents make decision on whether or not to do research on GRs, production process and pattern of interaction during access to GRs, their use and, thus, determine benefit-sharing (if any) in the end. There are three-levels of agents functioning in genetic resource management: biosphere, economy and biotechnology or genetic engineering (see Figure 2 on page 29). Each includes specific rights, obligations or responsibilities of agents and raise peculiar issues. Agents take genetic resources from "Biosphere" (1st level). Issue about *access to genetic resources* appears and should be solved at the stage of social interaction. Research on genetic resources is conducted, using capital and knowledge at the level "Biotechnology, Genetic engineering" (3rd special "core level"). Agents get outcome in the form of GMPs and begin to use them at the next level "Economy" (2nd level). Issue about *uncertainty and burden of proof* needs to be taken into account at these stages of genetic resource management. As a result, an agent gets benefit stream from all that activities and finally has to solve the issue about *benefit-sharing*. Thus, property rights in this field could be seen as social relations between stakeholders (owner of patent and others) about access to genetic resources, their use, benefit streams and responsibility, which is ensured by state.

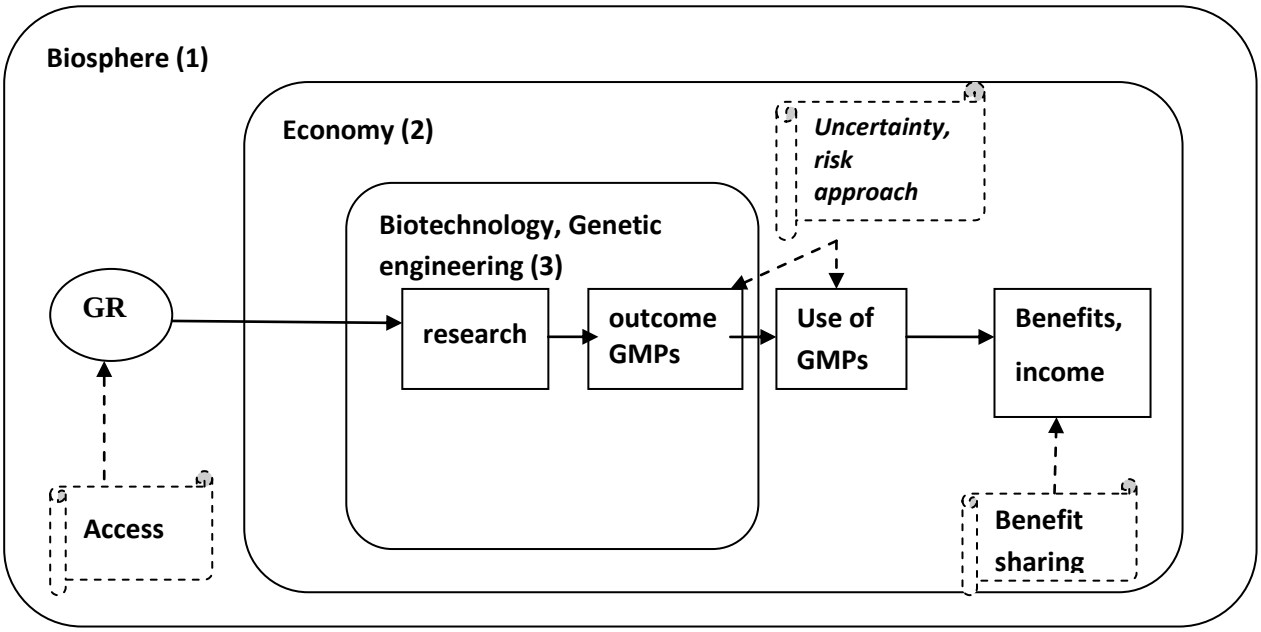


Figure 2: Three-levels functioning of agents in genetic resource management

Understanding pecularities in distribution of rights, preferences and values, and rationality held by agents (individual or social rationality) is important for analyzing institutional structure. Distribution of rights gives extra opportunities to carry out activities with GRs. So, property rights to GMPs determine who has access to GRs, how benefits are shared, who is responsibile and under what conditions.

The author also clarifies issues on coordination problems, real power of agents, allocation of benefits and costs of genetic engineering in Ukraine. It is necessary to understand the link between social, political, and economic factors of biotechnology development. Their influence on the choice by agents of the strategy of behavior is identified. Finally, obstacles for sustainable development of genetic engineering in Ukraine are revealed.

3.2. Risk and uncertainty theory

GMAPs have both advantages and disadvantages. Claimerd merits include resistance to pests and disease, tolerance to herbicides, cold, drought and salinity, nutrition. In addition, James O. Odek (1994) noticed: “These genetic resources make significant contributions to climate stabilization, watershed and soil protection, and maintenance of the earth's chemical balance.

Bioremediation, the use of specialized organisms to clean up pollution or environmental waste, is another area in which plant genetic resources can help protect the environment" (pp. 143-144). Such broad list of GMAPs advantages makes the tasks of GR management difficult. Even so, genetic engineering is higly responsible activity since man's health and the population's longevity is at stake: "According to WHO experts, a person's health is 50% dependent on socio-economic conditions and lifestyle, the most important component being food" (National Environmental Policy of Ukraine, 2007: 23). In particular, the professionals speak about the concern for biological security, "which is associated with the use of genetically modified organisms in food production. A well balanced diet of non-contaminated food is important in helping prevent oncological illnesses, with an impact of up to 35-50%, according to the WHO" (National Environmental Policy of Ukraine, 2007: 24-25). 'Disadvantages of GMAPs could be classified in the following groups: environmental hazards (unintended harm to other organisms; reduced effectiveness of pesticides; gene transfer to other varieties and wild species); human health risks (allergenicity; unknown effects on human health); and economic concerns (patenting issue)' (Whitman D.B., 2000: 5-8). Among socio-economic disadvantages of GR management there may be named the following:

- blockage of the development of other important technologies because of active financing of genetic engineering;
- access to GMPs and benefit for only certain (wealthy) people;
- negative affect of biotechnology on traditional agriculture;
- prevention of free idea exchange between scientists.

To understand the nature of disadvantages and their influence on the shaping policy, we should take into account the uncertainty, the "normal" thought processes which, according to Elizabeth O. Tiesberg (1991), "often lead people to illogical and incorrect conclusions" (p. 6). Uncertainty is associated with the absence of a precise answer as to the development of the ecosystem and its components in new conditions (like climate change, extinction of species, abiotic and biotic stresses, introduction of new and potentially harmful products into the environment). In addition, there are doubts about efficacy of newly produced GMAPs. They could cause negative effect on man's health and/or the environment.

Uncertainty and risk are widely examined in resilience theory. The resilience theory holds that the nature has a limited capacity to absorb and overcome anthropogenic harm. Threshold's prediction is almost impossible to do in GMAPs' case. Mario Giampietro (2001) wrote:

"When dealing with evolutionary processes it is impossible to ban uncertainty and ignorance from scientific models. Hence, traditional risk analysis (probability distributions and exact numerical models) becomes powerless. Other forms of scientific knowledge (general principles or metaphors) may be useful alternatives". Thus, establishment of the precautionary principle is prudent. According to Art. 8 (g) of the CBD, each Contracting Party shall "establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology, which organisms are likely to have adverse environmental impacts on the conservation and sustainable use of biological diversity, taking also into account the risks to human health".

Initially, the precautionary principle was claimed to be a tool of good environmental management, enhancing people's perception of the risks and uncertainty associated with the application of GMAPs. In addition, it was expected to stimulate research on GMOs as risk reducing measure. The principle includes three important elements: foresight, responsibility and uncertainty. Examining how national law on GR management reflects the aforementioned would help to identify environmental regime of certain country (in this case Ukraine), and the ways it combines with the trade regime. Establishment of the three elements of the precautionary principle in the national legal system was expected to provide the high level of independence, scientific excellence and transparency of research on GMO.

Elimination or decrease of uncertainty in GR management depends on the burden of proof. The burden of proof is a stumbling block between trade regime of the WTO (with private property issue) and environmental regime of the CBD (with precautionary principle). In order to define who has to bear future costs of damages, it should be identified who has the burden of proof concerning external effects according to international agreements on genetic resources. Taking into account natural characteristics of genetic resources, as an informational system (with functional units of heredity), and long-term lags of getting impact from using GMPs, it is difficult to prove or disprove negative impact of GMPs in this case. Burden of proof could be applied in genetic resource regime in two ways: 1) proof by the patent holder\owner that damage occurs (according to TRIPS); 2) proof by producer that results of genetic engineering will not imply shifting costs onto others (according to the CBD). So, we can agree with J.Lemons (1998): "Due to the difficulties involved in proving anything concerning biosphere dynamics – that is, the existence of radical uncertainty – the distribution of responsibility is crucial" (as cited in Vatn A., 2005: 271).

Burden of proof lays down a precondition for responsibility, as established by the law. The latter will be examined in light of efficiency of the legal regime of IPRs to GMAPs in Ukraine.

Chapter 4

METHODS

With biotechnology triggering institutional changes in ownership to GRs and creating conflict of stakeholder's interests, the subject of this thesis is controversial. The issue is approached as a social science study aimed at analysis of the conflict over access to GRs, and particularly, efficiency of implementing international law in developing countries' law. Data is collected using various research methods, mainly qualitative.

Ukraine is used as *a study location*. Instead of using questionnaire survey, the author analyzed legislation as a source. It is difficult to identify the implication of law in politically unstable conditions, thus, law may provide an artificial account of how a society operates. To compensate for this, data from media sources are used.

This comparative study has proved to be time-consuming with a big amount of legal sources to work on. It demands rigorous and simultaneous data collection and analysis. At the same time, the author has to stay focussed on the objective and the aim of the research. Coding helps to underline the main concepts and to identify categories.

This case study includes in-depth analyses of texts and events related to by ownership on the GRs in Ukraine. Author focuses on the key sources to understand the main points of the legal regime of IPRs to GMAPs and to disclose its advantages and disadvantages. Views on ownership of GMAPs are explored comparing national law to international treaties. Stakeholder's behaviour in GR management is documented through sources from mass media.

The legal regime on IPRs to GMPs is well established in Ukraine, but it does not stimulate science to produce GMAPs. Scientists are, therefore, categorized as *a focus group.* As a result, the author identified why their interests are not satisfied in Ukraine and what significant obstacles the policy creates for the development of genetic engineering there.

In addition to the manifest context, the author also looks for the latent context in the analysis; how language is used in the text, especially in mass media discourses. Reverse effect is observed generally in discussion about use of GMAPs in Ukraine. During the last 4-5 years the importance of organic food production is loudly highlighted, while benefits of genetic engineering are seldom mentioned. This could be a conscious omission or a statement that this branch of production is not developed in Ukraine. Either way this hampers progress, since without debate there will come no practical development.

The author proceeded stepwise as follows:

1. clarified the issue, aim, objective, the research questions and process of conducting research;
2. selected theories and conceptual frameworks;
3. developed the proposal and planned the writing process;
4. studied through literature review, and worked with data collection;
5. chose research design and methods;
6. identified and wrote findings;
7. summarized and explained the results in the discussion;
8. wrote conclusion describing the answers to the research questions.

The main points of research and drafts of the thesis have been discussed with the appointed supervisor. It should be noted that several steps (in particular, 3-7) above were actually repeated due to feedback from the supervisor.

This thesis describes the social relationships regarding GMAPs: through the general provisions of Ukrainian law. Basic understanding of the power of governance is also demonstrated. Subsequently it is illustrated that IPRs to GMAPs are mainly regulated by three branches of law in Ukraine. Finally key elements of these relationships are categorized: GRs, as an object of ownership; stakeholders as participants; mechanisms of IPRs to GMAPs as content of the relationships. The dominant discourse is why the patenting of the GMAPs does not progress in Ukraine.

4.1. Data collection

Research design evolved during the data collection. Data collection consists of a mixture of primary data and secondary data. The following *primary sources* are used: official documents (international treaties and Ukrainian laws, administrative regulations), cases and interviews.

Official documents are obtained through the government and state authorities' web-pages and compared with the opinions provided in mass media. Legislation reflects the national interests, which are laid down as the basis of the environmental policy of Ukraine. Alexandre Ch. Kiss and Dinah Shelton (2007) wrote that: "State practice must be general, although it need not be universal. State practice is identified through, e.g., official government texts and statements, court decisions, laws, and diplomatic exchanges… Conduct in violation of such official acts is treated as a violation of the law, not as extinguishing the custom. If a significant number of states adopt laws and official policies that lead them to act contrary to the purported rule, a new norm may emerge" (p. 8). This is clearly true concerning the legal regime of GRs, where case law is involved. Professional and bureaucratic viewpoints regarding issues of IPRs to GMAPs have been sourced through articles in newspapers and magazine, and on the Internet. This was essential for identification of stakeholder's interests and issues on the subject.

Secondary sources, used in this research, include books, articles, review of public documents (materials/reports), lectures, and encyclopaedias. Both print media and electronic media are used upon checking the document's trustworthiness. Critical approach requires the author to interpret secondary data from different sources. Exploring the published materials, the author considers the interests of the publisher and authors: what state authority and country they represent, and the source of financing the publication of their articles.

The author quantifies some data in order to explore relationships between variables, to show trends and identify obstacles. Both qualitative and quantitative findings are presented in this thesis.

Data collection involves *observation and archival (content) data.* Archival (content) data were needed mainly to understand historical background for settlement of the GRs legal

regime. The author's own work experience as a researcher in Ukraine is a sort of participant observation. This is one of the sources for describing the obstacles for development of science in Ukraine, which is also confirmed with facts found in governmental documents and articles.

Theoretical sampling generates the field data, which are sufficient for the research goal – to explore the contextual understanding of the IPRs to GMAPs at the national level and efficiency of its application. Theoretical sampling focused the research on a deeper understanding of the key points.

Grounded theory is applied to formulate findings of the research, which emerged from comparative analysis of the data. Common themes, which are found through application of coding, help to identify patterns.

Applying *open coding* to define concepts and categories in Ukrainian law, theoretical framework is formulated based on general knowledge of GR management. Though coding is used initially for analysis of interview data, it is also applicable to the analysis of dozens of laws. Texts of legislation and statistics form the basic units of analysis. For identification of distinct concepts and categories, *headings* are constructed for the first level concept, followed by *subheadings*, as second-level categories. *Highlights* are applied to distinguish and sort out concepts and categories both in relation to GRs and IPRs. The above outline can be seen clearly in Chapters 6 and 7.

Furthermore, *axial coding* is used to identify obstacles in the application of the legal regime of the IPRs to GMAPs in Ukraine. Concepts and categories are referenced to document how social and economic context influences the development of GR management in Ukraine, and what effects and consequences result. Transfer of concepts and categories into a data table in the draft assisted in formulating answers to research questions.

Legal regulation in Ukraine is constantly changing due to instability of the state. So, dynamic characteristics of grounded theory are relevant for exploring the Ukrainian legislation in some points. However, it does not have the dynamic trait of the interview that the results can be continually checked throughout all phases of the study.

Data collection was also initially planned as interviews with representatives from the state authorities, but due to warfare and instability in Ukraine this proved impossible. There is risk for personal safety, and the population is scared and suspicious of strangers. Instead, the research is based on written sources and the text analysis of articles.

To extend research and involve comparative analysis on the politics of GRs in the Russian Federation, an interview was conducted by email with Nikolai Kichigin, Candidate of Legal Sciences, Leading research fellow of the Institute of Legislation and Comparative Law under the Government of the Russian Federation (Moscow, the Russian Federation). Translation into English and deductions, based on the interview, have been sent to him for familiarization and approval of its validity. Per the interviewees permission, answers to the main questions from this interview are included in Appendix 1.

4.2. Discourse analysis

Discourse analysis plays a key role in the research for this thesis. Text linguistics and its interrelationship with the environment trigger stimulations or discouragements of agents to do the research on GRs and patenting of its results, which issue is also explored in this paper.

Discourse analysis is understood as "studies of the way people communicate with each other through language in a social setting, where language is not seen as a neutral medium for transmission of information, but is loaded with meaning displaying different versions of reality" (Walliman, 2006: 205-206). Moreover, discourse analysis is "also reminding us of the institutional, cultural or constitutive place of language. The terms remind us that words work for us because they are part of some wider phenomenon" (Hunt, A. & Wickham, G. 1998:8).

Discourse analysis addresses the social problem of access to and ownership over GRs. It is about interests and preferences of actors in shaping their arguments. As a result, the question of who has power and how it is exercised, when it is complemented by knowledge, is revealed. The author is mostly focusing on critical discourse analysis. As Van Dijk (2001) wrote, it is: "…a type of discourse analytical research that primarily studies the way social power abuse, dominance, and inequality are enacted, reproduced, and resisted by text and talk in the social and political context. With such dissident research, critical discourse analysts take explicit position, and thus want to understand, expose, and ultimately resist social

inequality" (p. 352). Discource analysis helps to explore the reciprocal relationship between ownership of GRs, as social phenomenon, and context of the environmental politics with its economic, social and cultural aspects.

Exploring legal rules using sociological tools has peculiarities. Shui (2001) explained it in the following way: "The area of law provides an open opportunity for discourse analysis, especially since law is such a highly verbal field. It is generally regarded as a field containing written discourse, for care is taken to record in print all oral interactions that occur in court. Cases are preserved in written form to serve as the basis for later decisions and to record the cases for later review. Law libraries, herefore, house immense collections of written text, such as motions, counterclaims, and judges' opinions, but they also contain spoken words, transcribed in writing, such as trial testimony, questioning, and argument" (p. 437).

Document analysis is applied to legislation text. To discover how law applies in practice and what arguments people have, discussions from academic literature and mass-media are used. Establishment and adjustment of the environmental regime of CBD and trade regime of TRIPS is supervised by meetings of the stakeholders. There were 12 meetings of the Conferences of the Parties on the CBD issues (web-site CBD) and numerous meetings on TRIPS issues (WTO web-site).

Use of languages: Since the thesis is written in English, translation from Ukrainian and some Russian sources is involved. The meaning of language is essential. Correct translation of notions without losing their initial meaning and intonation with which they have been pronounced or recorded plays a significant role and should be also saved in translation and interpretation of the meaning. In addition, law terminology has different meanings compared to sociological terminology. For instance, the terms "ownership" and "property rights" have more precise and practical meanings in law. They address the rights and obligations related to something (for example, GMPs), while sociologists emphasize, first of all, the special link between owner and the object of ownership, and his/her relationship with other people relative to this object.

Overall, the thesis illustrates an example of how implementation of IPRs to GMAPs could be done in the developing country subject to its national interests, economic and social dimensions.

Chapter 5

LEGISLATION ON GENETIC RESOURCE MANAGEMENT

Law of Ukraine "On Seeds and Planting Materials" of December 26, 2002 No. 411-IV states that legislation on seeds and planting materials "does not extend to turnover of seeds and planting material of genetically modified organisms (plants)" (Preamble). GR management is regulated by a special legislation in Ukraine. It includes environmental legislation, the Civil Code of Ukraine and the Economic Code of Ukraine of January 16, 2003 (hereinafter - ECU). They regulate different aspects of GR management.

In whole, legal regulation of IPRs to GMAPs should ensure effective use of the national scientific, technical and intellectual potential. It should foster competitiveness of a country in the world market through support of national economic development. Therefore, stimulation of innovative development should be at the core of state policy. At the same time, stable social and legal policy establishes a good base for the development of innovations.

Taking into account unstable economic and political life, differences in features of animals and plants, the Ukrainian government establishes separate national programs periodically. For instance, the Nationwide selection programs in livestock breeding are developed every 5-10 years. They are obligatory for the subjects of pedigree livestock breeding (Article 8 of the Law of Ukraine "On Pedigree Work in Livestock Breeding" of December 15, 1993 No.3691-XII).

The Ukrainian legislation on IPRs to GMAPs establishes a hierarchical system of legal acts and consists of the Constitution of Ukraine (1996), the Civil Code of Ukraine (2003), Economic Code of Ukraine (2003), laws and acts of the President of Ukraine, resolutions of the Cabinet of Ministers of Ukraine, the regulatory legal acts of the ministries and other public authorities of Ukraine, and acts of local state administrations. IPRs to GMAPs are regulated equally in all territory of Ukraine, and the law is obligatory for fulfillment by everybody (Art. 4 of CCU).

In this chapter overview of legislation on GR management in Ukraine is made taking into account its division by the tasks of state policy (f.i., ensuring environmental safety, freedom of business activity, etc.) and nature of human activity (environmental or economic activity).

5.1. Environmental legislation of Ukraine

The issues of human rights, mentioned in the international conventions and recommendations of the International Committee on Bioethics of the UNESCO, have been considered in the adaptation of the legal norms on biotechnologies in Ukraine. In particular, the precautionary principle has been laid down as the basis of environmental legislation. According to the "National Environmental Policy of Ukraine: assessment and development strategy" (2007): "compared to the constitutions of EU member-states, the Constitution of Ukraine is distinguished by a significantly higher level of ecological regulation, especially in guaranteeing citizens the right to an environment that is safe for life and health" (p. 72). Ukrainian law declares the right of everyone to the environment, which is safe for life and health, and to compensation for damages inflicted through the violation of this right. "Everyone is guaranteed the right of free access to reliable information about the state of the environment, the quality of food and consumer goods, and also the right to collect and disseminate such information" (Art.50 of the Constitution of Ukraine, 1996). "Human and citizens' rights and freedoms affirmed by the Constitution are not exhaustive. Constitutional rights and freedoms are guaranteed and shall not be abolished. The content and scope of the existing rights and freedoms shall not be diminished in the adoption of new laws or in the amendment of laws that are in force" (Art. 22 of the Constitution of Ukraine, 1996). Art. 21 of the Constitution of Ukraine (1996) specifies: "All people are free and equal in their dignity and rights. Human rights and freedoms are inalienable and inviolable". Overall, Ukraine was the first among the post-Soviet countries, which legally determined a wide range of citizens' ecological rights (Art. 9 of the Law of Ukraine "On Environmental Protection", 1991). Special legislation has been carried on the development of the fundamental principles of the Law of Ukraine "On Environmental Protection" (1991).

The sustainable economic and social development of Ukraine is seen in light of achievement of a harmonious interaction between society and nature, the rational utilization of natural resources, and the maintenance of environmental safety for the vital activities of man.

Environmental protection in Ukraine is organized as a part of the state policy to preserve the environment, maintain harmlessness for the existence of animate and inanimate nature in the interests of the present and future generations. So, Art.3 of the Law of Ukraine "On State Biosafety System for Developing, Testing, Transportation and Use Genetically Modified Organisms" of May 31, 2007 No.1103-V (hereinafter - Law of Ukraine "On State Biosafety System for Developing, Testing, Transportation and Use Genetically Modified Organisms", 2007) declared that: "The basic principles of state policy on genetic engineering activity and GMO handling are: priority of protection of human health, conservation of environment compared with obtaining economic benefits from the use of GMOs".

The legislation on the national biosafety system regulates production, test, transport and use of GMOs. In particular, it adresses issues about the effectiveness of genetically modified food labeling, and enhancement of coordination of GMP's turnover.

Enterprises, institutions and organizations are obliged to ensure ecologically safe production. In particular, they should develop and implement measures for the prevention and mitigation of the consequences of harmful effects of biological factors on the environment and the health of people. Additionally, biological and genetic safety is maintained through state control (Art. 35 of the Law of Ukraine "On Environmental Protection", 1991).

Precautionary principle has been specified in Article 53 of the Law of Ukraine "On Environmental Protection" (1991): "The production and utilization of new strains of microorganisms and other biologically active substances, including the GMOs and products received as a result of use of strains of microorganisms, shall be carried out only after comprehensive research and based on evaluation of their effect on the health of people and the environment". Appropriate standards and methods of detecting permissible concentration of GMO in the environment and food products also have been settled.

5.2. Civil legislation of Ukraine

In contrast to Civil Law of Ukraine, environmental protection is considered in environmental legislation regarding both the environment and a man. Protection of the environment and persons' life and health are of the utmost value in the Ukrainian society. Civil Law of Ukraine

is focused on safe environment in the context of the man's right to safe environment (Art. 293 of CCU). In particular, Art. 293(3) of CCU states: "A natural person shall have the right to safe consumer products (food products and articles of everyday life)". Overall, in enjoying the rights and performing the obligations *the owner shall be obliged to meet the moral principles of the society* (Art. 319 (2) of CCU). Art. 201 (1) of CCU specified that life and health; authorship; scientific and technical creative work and other benefits, as personal non-property benefits, are protected by the civil legislation.

Provisions of CCU are applied to the regulation of relations on the use of natural resources and the environmental protection in the property rights' context (Art. 9 of CCU). GMPs as results of intellectual and creative activity, which contain valuable information, as well as other tangible and intangible property are the objects of civil rights (Art. 177 of CCU). Their production and turnover create civil rights and obligations. The key civil right - the ownership right - includes statement that the owner shall have the right to own, use and dispose of his property (Art. 317 (1) of CCU). In whole, concept of ownership in Ukraine is based on the traditions of Roman law.

The matters affecting the availability, acquisition, scope, maintenance and enforcement of IPRs as well as those matters affecting the use of IPRs should be included in the protection of IPRs. The task of enforcement and protection and of IPR's consists in: 1) the promotion of technological innovation; 2) the contribution to the transfer and dissemination of technology; 3) the support of mutual advantage of producers and users of technological knowledge in a manner conducive to social and economic welfare; 4) the balancing of rights and obligations (Art. 7 TRIPS). The term of IPR's protection, according to Art.33 TRIPS, is twenty years counted from the filing date. Ukraine implemented the provisions of TRIPS, taking into account national interests, peculiarities of the legal system, the level of the state development and matters of historical significance, such as legal force of the inherited Soviet patents.

Book 4 "Intellectual Property Rights" of CCU includes rules about both patents and Plant Breeder's Rights (hereinafter – PBRs, which are established by the International Union for the Protection of New Varieties of Plants (UPOV) in the International Convention for the Protection of New Varieties of Plants of December 2, 1961). Legal terminology for identification of their elements is also used in a general way. Ukrainian legislation does not distinguish between IPRs to GMPs and PBRs, but introduces a variation of mechanisms for

protection of plant varieties (patenting or registration of Plant/Animal Breeder's Rights). At the same time, a genetically modified variety can be produced with help of technologies which could be considered as patentable inventions. Therefore, a variety protected by PBRs may contain patented technology. Such cases have not occured in Ukraine to the author's knowledge, they have however in Canada (e.g., case *Monsanto Canada Inc. v. Schmeiser*, 2004) and the USA (e.g., case *Ex Parte Hibberd*, 1985), which allows utility patenting and, as a result, "over 1,800 patents in plant germplasm were granted" (Maguire J. Wai-Shing, 2012: 61). The reasons for this will be investigated below.

Generally speaking, with establishment of property rights to GMPs, GR management became profitable. To explain this, there are the following words of Arild Vatn (2005): "*Property rights* imply a guarantee for the acquisition of benefit streams from specific resources. This institution gives this benefit to the rights holder, and by creating such an arrangement there will in principle be no uncertainty about the distribution of the benefits. This reduces costs since the property holder does not need physically protect what s/he defines as hers/his. Instead the collective/the state, after having acknowledgment the exclusive right, protects it by the law. This considerably reduces the cost of protection born by the individuals – their transaction costs" (p. 176). So, as a result of the need for new rules and disciplines concerning protection of IPR's to GMPs, a new institution of patenting has been created subject to the differences in national legal systems.

Art. 3 of CCU establishes the principles of civil legislation. Some of them also should be applied to the patenting of GMAPs in Ukraine: inadmissibility of deprivation of the property right, except the cases established by the Constitution of Ukraine (1996) and the law; freedom of the agreement; freedom of the business activity which has not been forbidden by the law; judicial protection of the civil law and interest; justice, integrity and rationality.

The Protection of intellectual property is identified as one of the tasks on the way of integration of Ukraine into the EU together with *the Selective work* and *th*e *Genetically modified organisms* (Clauses 6.1.3., 8.2.4., 11.1.5. of the Programme of Integration of Ukraine into the European Union approved by the President's Decree of September 14, 2000 (hereinafter - Programme of the Ukrainian Integration, 2000).

5.3. Economic Code of Ukraine and genetic engineering

As inventions, GMPs are under regulation of ECU. In particular, it was stated in Art. 154(1), 156(6) that the Code regulates relations associated with the exercise and protection of IPRs (including rights to plant varieties and species of animals) in economic activity (e.g. in case of the right of the invention's priority use, transfer of the rights to use invention as a contribution to the enterprise's authorized fund).

Similar to Canadian Patent Law, Ukrainian patent legislation treats all inventions equally. Peculiarities of GMAPs are not taken into account, though some facts from the cases on IPRs to GMAPs should strike a warning note: "Inventions in the field of agriculture may give rise to concerns not raised in other fields - moral concerns about whether it is right to manipulate genes in order to obtain better weed control or higher yields" (Clause 93 of case *Monsanto Canada Inc. v. Schmeiser*, 2004).

ECU also regulates competition issues which occurred to be intrinsic to GR management. In this case, William E. Kovacic and Andreas P. Reindl (2004) wrote: "…IP regimes and competition law and policy intersect - and therefore require coordination - in two areas. On the one hand, the definition of IPR and the circumstances in which IPRs are granted may affect competition. Poorly functioning IP regimes distort competition and may chill innovation. On the other hand, competition enforcement affects how IPR holders can use their rights. Poorly functioning competition law and policy at the interface with IPRs can distort IP-based innovation" (pp. 1062-1063).

ECU contains a provision that it shall not apply to property or the private non-property relations regulated by CCU, as well as land, mining, forest and water relations, use and protection of flora and fauna, natural reserves and atmospheric air (Art. 4 (1) of ECU). Overall, legal regulation of IPRs to GMPs consists of complex set of rules from different branches of law. They supplement each other and specify rules for appropriate activity.

Chapter 6

GENETIC RESOURCES AND STAKEHOLDERS

In this chapter the legal regime of GRs as common-pool resources is discussed in relation to issues of private property by virtue of patenting. The main points regarding ownership and user rights to GRs are investigated, too. Analyzing formal legal and institutional frameworks for GRs, the author explores how rights, obligations and responsibilities of stakeholders are distributed across GR policy at the international and national level, Ukraine being taken as an example.

6.1. Genetic resources as an object of Intellectual property rights

Treating genetic diversity as a global resource becomes obsolete with change of practice regarding *the free access to the seeds and breeding animals.* To coordinate use of GRs, and particularly, to ensure access to them, stakeholders established sovereignity rights and property rights on GRs in the CBD and the TRIPS. Thomas Cottier (1998) noticed: "It is submitted that the distinction between sovereign rights and private rights in accordance with a distinction between genetic resources of potential use, and existing knowledge, could help to further clarify such principles and rights, and direct the allocation of revenues to states on the one hand, and individuals and communities on the other hand" (p. 576). The Supreme Court of the State of California held in case *Moore v. Regents of the University of California* (1990) that: "The genetic information, as it exists, therefore remains in the public domain, unless altered by a patentable invention." (Cottier, T. 1998: 568) The fact that people could legally treat GRs, and derivatives, obtained from them, as goods, raised more issues from point of view of environmentalists. Natural resources cannot be substituted by other things. They cannot be evaluated in monetary form as well. Considering natural resources as goods, Karl Polanyi underlined in his work 'The Great Transformation: The Political and Economic Origins of Our Time' ([1944] 1957): "creating markets is foremost a transformation of the complex qualities of the involved objects into commodities with a specified price" (as cited in Vatn A., 2005: 14-15).

Above mentioned point of view responds to the discussion between environmentalists and economists about value of GRs as particles of nature and goods. To understand nature and scope of IPRs to GMAPs in Ukraine, we should, first of all, analyze legal status of GRs. After that, it will be possible to recognize features of IPRs to GMAPs in Ukraine.

GRs, as elements of natural resources located within the boundaries of Ukraine, its continental shelf, exclusive (marine) economic zone, are objects of ownership right of Ukrainian people (Art. 13 of the Constitution of Ukraine, 1996, Art. 324 (1) of CCU). The ownership right to resources and right to manage them on behalf of the state within the limits established by law belong to the state authorities and local governments (Art. 324 (2) of CCU). At the same time, according to Art. 324 (3) of CCU: "every citizen shall have the right to use the natural objects of the ownership right of Ukrainian people pursuant to the law".

Microorganisms and non-biological and microbiological processes are eligible for patenting. So, Nikolai Kichigin (2014) specified: "Article 1350 of the Civil Code of the Russian Federation defines the conditions of patentability of the invention. Technical decision is protected as an invention in any industry in respect of the product (particularly the device, substance, strain of microorganism, cultures of cells of plants or animals) or method (process of execution of the actions on material object by means of funds)… The comments to the Civil Code of the Russian Federation state that the *substances* include – chemical compounding such as nuclear proteins and acids; compositions (mixture, speciation); products of nuclear transformation. *Strains of organisms* include strains of bacteria, viruses, bacteriophages, microalgae, microfungus, consortiums of microorganisms. *The lines of the cells of plants* and animals include the lines of the cells of tissues, organs of plants or animals, consortiums of correspondent cells. The genetic constructions include plasmids, vectors, stable transformed cells of microorganisms of plants and animals, transgenic plans" (Appendix 1: Interview with Nikolai Kichigin, 2014). Ukrainian law does not have so wide definition of the conditions for patentability of the invention in CCU.

Art. 27(3-b) of TRIPS entitles governments to exclude from patentability "plants, animals other than micro-organisms, and 'essentially' biological processes". Such definition corresponds to the understanding of discovery that cannot be patented in some countries. Identification of innovation as invention or discovery influences the possibility to patent it. Members of WTO may also exclude from patentability inventions with aim to protect *ordre*

public or morality, "including to protect human, animal or plant life or health" or to avoid serious prejudice to the environment within their territory (Art. 27(2) of TRIPS). For example, Nikolai Kichigin (2014) pointed out that "the following cannot be objects of patent rights in the Russian Federation:

1) the ways of cloning people;
2) the ways of modification of genetic unity of cells of human germ line;
3) usage of human embryos for industrial and commercial goals;
4) other patent claims that may contradict social interests and principles of humanity and morality" (Appendix 1: Interview with Nikolai Kichigin, 2014).

The establishment of such rules in Ukrainian legislation is higly debated recently by experts from different fields of science, deputies and non-governmental organizations.

In general, *object of IPRs* is understood as a result of intellectual and creative activity, expressed in an objective form or fixed on a particular physical medium, including electronic. According to the Ukrainian legislation, they include: data compilation (database); scientific discoveries; inventions; plant varieties and animal breeds; etc. (Art. 420 (1) of CCU). Such definition of the objects of IPRs is tricky. The same object can be covered by different categories depending on its characteristics and functions in economic and social relationships. GMAPs could be recognized as inventions or registrated as plant varieties/animal breed. In particular, Art. 11(1) of the Law of Ukraine "On Protection of Rights to Plant Variety" (1993) specifies: "*Varieties of the sort* that can be covered by the right (IPRs – *O.Ch.*) may be clone, first generation hybrid, population". Art. 1 of the Law of Ukraine "On Animal Breeding" of December 15, 1993 No. 3691-XII identified *breeding achievement* that can be protected by IPRs as "a group of breeding animals (species, breed type, line, family, etc.) created as a result of targeted creative work that has new genetic traits which consistently are transmitted to posterity, and exceeds performance of previous types of animals by productivity index". This definition correspond to such criteria of protection of breeder's rights, as Novelty, Distinct, Uniform, and Stable (hereinafter - NDUS), identified in Chapter III of the International Convention for the Protection of New Varieties of Plants (1961).

In comparison to TRIPS, microorganisms, non-biological and microbiological processes are not mentioned in the Ukrainian law separately as objects which are eligible/not eligible for patenting. A similar situation is observed in the Russian Federation: "The genetic resources are not directly defined as the objects of patent rights in the Civil Code of the Russian

Federation (part 4). The term ‘genetic resources’ is not used in the Code. However, according to Article 1349 of the Civil Code of the Russian Federation, the objects of patent rights are the results of intellectual activity in science and technology industry which meet the requirements for inventions and useful models established by the present Code and the results of intellectual property in regard to design which comply with the requirements for industrial units established by the Code” (Appendix 1: Interview with Nikolai Kichigin, 2014).

TRIPS has legal force on equal basis with national law of Ukraine, as was mentioned in Chapter 2.1. of this thesis. Thus, patenting of microorganisms, non-biological and microbiological processes is possible, if they fall into the category of scientific discovery, inventions, and so on. In addition, it should be mentioned that Ukrainian law does not contain definition of the scientific discovery in its traditional meaning as an object for patenting. Taking into account descriptions of conditions for patenting of the scientific discovery, the latter should contain the elements of the invention.

Taking into account the above mentioned, there is overlapping of legal regimes: the legal regime of the inventions, and the legal regime of the plant varieties\animal breeding. The latter has priority over the former due to the special nature of its provisions relative to GRs and the environment in whole. In more general context, the regime of CBD is overlapped by the regime of TRIPS. It leads to conflicts between developed countries and developing countries. Their different values, preferences and interests lay behind a number of conflicts.

The CBD established principles of access to genetic resources and benefit sharing (Art. 15 CBD). Access to genetic resources shall be subject to Prior Informed Consent (PIC) which shall be made on mutually agreed terms. Benefits arising from the commercial and other utilization of genetic resources, as well as the results of research and development, and technology shall be shared in a fair and equitable way upon mutually agreed terms, multilaterally or on a bilateral basis. Transfer of technologies relevant to the conservation of biological diversity, and access to the sustainable use of its components and to technologies that make use of genetic resources shall be provided and/or facilitated under fair and most favorable terms. Benefit-sharing agreements need to comply with the general aims of the Convention. In particular, any benefit-sharing regime should ensure the involvement of the holders of the resources and related knowledge. The benefits may be shared in cash or other

forms, such as monetary benefits, royalties or access to (bio)technologies developed with the genetic resources, technology transfer, training or support of research.

An international regime on access to genetic resources, the fair and equitable sharing of benefits derived from their exploitation are seen as the obligatory provisions of Access-benefit sharing agreements (ABS agreement) or Material Transfer Agreement. The level of economic development of the parties to the agreement (developed countries or developing countries) and the differences in geographical location of providers of genetic resources, as well as the biological features of genetic resources define the peculiarities of corresponding agreements. Particularly, Tadesse Gebreselassie Abeba (2009) noticed that: "The details of the measures taken by different countries may differ, depending on the need, capacity and choice of each country" (p. 77).

Madagascar vs. Eli Lilly, the USA is a typical case on polarity of interests of "North-South" countries. Madagascar's Rosy Periwinkle plant is a product of Madagascar's unique evolutionary history. Madagascar, like Australia or the Galapagos, is an evolutionary haven with one of the most distinctive ecosystems in the world though it has lost 93% of its forests due to reckless development. The development of the alkaloids vincristine and vinblastine from Madagascar's Rosy Periwinkle plant provide a cure for Hodgkin's disease and acute lymphocytic leukemia. The value of vincristine and vinblastin is estimated at over $200 million per year. They also generate hundreds of millions of dollars in revenue annually for its developer, Eli Lilly (at least $160 million). Madagascar receives nothing (Michael D., 1999: 11-12).

Ukraine is a part of Europe geographically. It has a moderately continental climate and is rich in biodiversity. "In spite of the fact that Ukraine covers less than six percent of the area of Europe, it contains approximately 35 percent of its biological diversity, which is aided by Ukraine's placement at the crossroads of many natural ecosystems, migration paths of fauna and a wide array of flora" (National Environmental Policy of Ukraine, 2007: 8). Ukraine is represented by species which live in the temperate forest's zone, deciduous forests, forest-steppe zone, and steppe zone, Carpathian Mountains, Crimean Mountains, Black Sea and Azov Sea. Some species are common for other European countries which have the same climate and/or are neighboring countries. Exercising sovereign rights over GRs, which occur on the border with other countries, is a debatable question nowadays. So, Dan Leskien and

Michael Flitner (1997) pointed out: "The fact that genetic resources are replicable and that many genes occur in more than one country has considerable implications for the realization of a country's sovereign right over its genetic resources. While in such cases one may argue that each of two or more countries of origin has sovereign rights separately, it is also clear that these rights do not extend to each other's resources. Thus, sovereign rights over genetic resources can be of an exclusive nature only if the resources occur in not more than one country, or if all countries of origin have agreed to exercise their rights jointly… While the sovereign right of states over their genetic resources is no longer questioned, it should be noted that it may be very difficult to exercise this right in practice. Difficulties in exercising a right do not limit the right as such; they may, however, render this right less significant" (pp. 36-37)". In addition to the legal issue on the definition of sovereign rights on cross-border GRs, the European entities officially do not show much interest in getting GRs from Ukraine to produce GMAPs. Perhaps, this is due to free access to GRs with less bureaucracy from other European countries or even from the own environment.

GMPs, as an object of IPRs, could also be classified as *an object of the invention.* It represents a new type of competitive product or process in any field of technology, which is implemented in the industry and social relationships (Art. 459 (2) of CCU, Art. 327(1) of ECU, Art. 3 (1) of the Law of Ukraine "On Innovative Activity" of July 4, 2002, No.40-IV (hereinafter - Law of Ukraine "On Innovative Activity", 2002). "Business entities shall have the right of priority use of the invention, according to terms provided by the Civil Code of Ukraine" (Art.156(4) of ECU), especially if it would help them to be efficient and environmentally friendly. Development of innovations could lead to improvements in social life provided that productive forces and progressive inter-sector structural changes are also involved. Innovative activities mean investments in scientific research and development.

To understand the development and goals of GR management in Ukraine, one could look at the description of *the objectives of pedigree livestock breeding*, given in Art. 6 of the Law of Ukraine "On Pedigree Work in Livestock Breeding" (1993), as on the example:

- creation, preservation, reflection and rational utilization of pedigree (genetic) resources of the highest genetic value for improving pedigree quality of an animal, enhancing economic efficiency and competitive ability of the field;
- obtainment of animals with new high genetic traits;
- effective use of the most valuable genetic resources of improved breeds;

- formation of its own export potential of pedigree (genetic) resources;
- preservation of gene pool of existing, local and disappearing domestic breeds;
- ensuring of genetic diversity;
- introduction of scientific and technical achievements in genetic researches, selection and animals' reproduction into manufacture;
- creation of selection achievements, and others.

Since innovation activity has a wide range of objects, and state budget of Ukraine cannot finance marketing all of them, the Parliament prioritizes fields of innovation activity via Priority Orientation. The orientations are classified into strategic and mid-term. Strategic orientations are approved by the Parliament of Ukraine for a period of 10 years. Mid-term orientations are defined for a period of 5 years and aimed at the performance of the strategic priority orientation step-by-step at the national, district and regional levels (Art. 2(2), 5 of the Law of Ukraine "On Priority Orientations of Innovative Activity in Ukraine" of September 8, 2011 No. 3715-VI (hereinafter - Law of Ukraine "On Priority Orientations of Innovative Activity in Ukraine", 2011). The Strategic Priority Orientations for 2011-2021 include both supportive and controversial provisions for development of IPRs to GMAPs in Ukraine: technological renewal and development of agricultural industry; wide usage of clean technologies for manufacturing and protection of environment, and others (Art. 4 (1) of the Law of Ukraine "On Priority Orientations of Innovative Activity in Ukraine", 2011). At the same time, *the following fields of development of science and engineering were identified as preferred through 2020:* conservation; life science, innovative technologies of prevention and treatment of the common ailments; innovative substances and materials (Art. 3 of the Law of Ukraine "On Priority Directions of Development of Science and Engineering" of July 11, 2011). Thus, both conservation of the nature and an innovative development should be a priority for state development in Ukraine, at least until 2021.

An innovative product should meet the requirements, established in Art. 14 (1) of the Law of Ukraine "On Innovative Activity" (2002):

a) It should be an implementation of an object of intellectual property (innovation, selection, achievement etc.), according to the protection documents (patents, certificates) or licenses granted by the owner of intellectual property, or implementation (introduction) of the innovations;

b) development of the appropriate product enhances domestic scientific, technical, and technological level;

c) it should be produced in Ukraine for the first time; or if not for the first time, then compared with other similar products placed on the market, the innovative product should be competitive and have higher technical and economic indicators.

Thus, the above mentioned provision of the Ukrainian law reflects Art. 59 (1) of CCU, stating that "*[a]n invention* shall be deemed eligible for acquisition of the intellectual property right to it, provided it is new, has an inventory level (is non-obvious, according to Art. 27 of TRIPS – *O. Ch.*) and is eligible to industrial use pursuant to the law (is "useful", according to Art. 27 of TRIPS – *O.Ch.*)". According to Art. 27 of TRIPS: "…patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced".

In some cases the law may determine that the products and the processes are not eligible for acquisition of IPR to them (Art. 459 (3) of CCU), as in the case with matters specified in Art.27 (3) of TRIPS (on plants and animals other than micro-organisms, and essentially biological processes). Moreover, the product or process can be eligible for acquisition of IPRs to them, yet still be prohibited for distribution in Ukraine (mainly because of environmental safety concerns). Decisions whether to qualify product as innovative are made by the central executive authority, which implements state policy in the field of innovative activity upon results of examination (Art.14(2) of the Law of Ukraine "On Innovative Activity", 2002).

Estimating the value of GRs, as an object of patenting, is a difficult task because the value of raw GRs is often latent. As James O. Odek (1994) wrote: "…in extractions involving minerals, timber and allied resources, value is appropriated in direct proportion to the volume of the resource extracted. With plant genetic resources, however, the value of the whole is present in even minimal amounts" (pp. 156-157). Nowadays pricing of GRs, as an object of patenting, performed by the "patent valorisation" approach: " Accordingly, the term "patent valorisation" refers to the action of creating value from patents by capturing and extracting their latent economic potential through developing and commercialising the underlying technology" (European Commission, 2012: 4). According to Ukrainian law, the objects of the IPRs could be included in accounting through the *estimation of the economic value of the IPRs* (Clause 1 of Procedure of the Estimation of the Assessed Value of the Intellectual

Property Rights Which Belong to the State Property or Were Created (Acquired) for Public Funds to Enroll in the Accounting approved by the Order of the State Property Fund of Ukraine of December 13, 2005 No.3162). The cost of the IPRs to GMPs is determined according to the results of the inventorying. Taking into account special status of the object of the IPRs which have sensitive information, management by them (including their evaluation) shall be made in accordance with the requirements of the Law of Ukraine "On the State Secret" of January 21, 1994 No.3855-XII.

Ukrainian law distinguishes between the legal status of GMPs made for state budget or private means. For example, *foreign patenting* of technologies or their components, made for state budget means, should be funded by private enterprises, scientific institutions or organisations or by other funds which are not forbidden by law (Art. 13 (1) of Law of Ukraine "On State Regulation of the Activity in the Field of Technology Transfer" of September 14, 2006). Thus, Ukrainian scientific schools could be promoted in the world in such a way.

The Cabinet of Ministers of Ukraine publishes the list of the plants varieties the rights to which has belonged to the owner of variety over some period of time. Surprisingly, in the List of the Varieties of Plants the Rights to Which Belong to the Patentee Over the Period of 2006, approved by the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183 there have been mentioned some vegetables and plants which are included in the everyday diet of Ukrainians: "Eggplant (*Solanum melongena L.*), Garden's/Vegetable's Beetroot (*Beta vulgaris L. ssp. vulgaris var.conditiva Alef.*), Sugarbeet (*Beta vulgaris L. ssp. vulgaris var. altissima Doell.*), Melon (*Cucumis melo L.*), Rye (*Secale cereale L.*), Watermelon (*Citrullus lanatus (Thunb.) Matsum. et Nakai*), Cultivated Cabbage (*Brassica oleraceae L. convar. capitata (L.) Alef. var. alba DC.*), Potatoe (*Solanum tuberosum L.*), Maize (*Zea mays L.*), Carrot (*Daucus carota L.*), Soft Wheat (*Triticum aestivum L.),* Rice (*Oryza sativa L.*), Sunflower (*Helianthus annuus L.*), Soya (*Glycine max. (L.) Merr.*)", and others. Popularity of these kinds of plants among Ukrainians is due to some benefits, like resistance to disease, or tolerance to weather conditions.

Analyzing application of IPRs to GMAPs in Ukraine, N.Malysh (2013) summarized: "Low level of protection of intellectual proprietary rights prevents wide usage of GMO seeds in agriculture in Ukraine. Mainly, it covers wheat and rape seeds while hybrid seeds of corn and

soya are already placed on the market" (p. 119). Linking this situation to the economy, Irina Lutsenko (2013) points out: "Nowadays everyone knows that one of the major problems with Ukrainian agriculture is lack of quality sowing material. High productive varieties of crops are expensive but they yield fruitfully while cheap varieties, bought by farmers due to lack of money, decrease crop capacity along with the quality of the crop" (Lutsenko I., 2013). As Irina Sadova (2014) mentioned: "Competition depends on the effective use of a hectarage of land applying crop capacity and production costs. There is a critical line, where competitiveness is decreasing due to the decrease of the price. The relative cost of seeds increases and becomes critical. Thus, there is a risk that our manufacturers will compose 20-30% of the production costs instead of 12-18%". So, an economic benefit from using GMPs is visible in the short-term perspective, but nobody can predict its ecological and social effects on the long-term scale. This is why some people have biases against genetic use restriction technologies (hereafter – GURTs or "Terminator" mechanisms). GURTs control the molecular mechanisms. In turn, the latter regulates genes: "Genes can be inactive (turned off) or active. When a gene is activated the instruction in the gene is read and the gene product produced. GURTs depend on switch mechanism that turn a seed-killing gene off resulting in viable seeds or on resulting in sterile seeds" (FAO Commission on Genetic Resources, 2002). Thus, the mechanisms of control and ownership over GRs are developing by means of law and technology.

On one hand, GURTs help to solve issue of controllability of access to genetic resources. Dan Leskien and Michael Flitner (1997) explained it clearly in the following way: "[A]ccess laws are only as good as the possibilities to control compliance with them… Controlling compliance with access legislation is especially difficult because seeds are small and their removal is almost impossible to control physically. A small number of seeds having illegally left the country may suffice to deprive that country of its actual control over the resource. Losing control over the resource does not of course mean that the country is also deprived of its sovereign right. It means, however, that the tool for exercising this right, which is exclusive control over the resource, is no longer available" (pp. 36-37). On the other hand, ethical questions on the distribution of costs and benefits have long been discussed.

Along with negative sides of using GURTS, as controller of access to GMPs, there is a positive one. GURTS could help to prevent genetic erosion of neighbouring fields. So,

environmentalists will have fewer reasons to be worried about environmental safety. Courts will have less complicated cases on GMPs, too.

According to Stephen Hubicki and Brad Sherman (2005): "More than 50 patents have been granted worldwide covering various genetic use restriction technologies" (p. 267). The figures show tendency in the development of GR management and give grounds for present conflicts between supporters of environmental regime and trade regime.

Fullfilment of environmental regime is controlled by the state bodies in Ukraine. Plant varieties are subject to public inspection aimed at evaluating the possibility of its suitability for distribution in Ukraine. In particular, the government has established a scientific-methodological centre on issues of GMO's examination - *Institute of Food Biotechnology and Genomics of the National Academy of Sciences of Ukraine* (Ordinance of the Cabinet of Ministers of Ukraine of October 10, 2012 No. 761-p). In addition, a network of testing laboratories for definition of GMO's content in products has been established, too (Regulation of the Cabinet of Ministers of Ukraine of July 7, 2013 No.700).

According to Clause 2 of *the Criteria of the Prohibition to Distribute Varieties in Ukraine (2002),* the criteria are applied to varieties, which:

1. Are not suitable for state protection (i.e. do not comply with the criteria of UPOV).
2. Do not satisfy needs of society.
3. Threaten health and life of people.
4. Affect flora and fauna.

Such provisions in the Ukrainian law prove that legislation about application of patented varieties reflects the precautionary principle. Consideration of abovementioned *criteria is obligatory* for all stakeholders that approach Derzhsortservice (English - the State Variety Service). Every genetically modified variety should be officially registered in *the Registry of Plant Varieties suitable for distribution in Ukraine* in order to be imported or cultivated legally (Clause 1.3 of Criteria of the Prohibition to Distribute Varieties in Ukraine; Clause 1 of Chapter V of Order of the Ministry of Agrarian Policy and Food of Ukraine of August 16, 2013 No.503). Unfortunately, practice is different. Foods containing GMO are not growing officially in Ukraine, as proved by the following data: "There are 37 laboratories in Ukraine. 15 of them belong to Ukrmetrteststandart (Ukrainian state research and production center for standardization, metrology, certification and consumers' rights protection – *O.Ch.*). Such

laboratory tests 10 specimens of products for GMO presence per day. An analysis takes 2-3 days. According to the data of laboratories 3% of tested products contained GMO in 2011" (Malysh N., 2013: 119). If each of the 15 labs mentioned above works 250 days a year this would mean 37500 samples tested annually of which 1125 contained GMO.

GMOs have been released to the food production chain illegally. For instance, genetically modified potatoe was imported into Ukraine for field research in the 1990's. Considering the terrible social, political and economic circumstances of that period, it was impossible to provide control for its proper use. As a result, genetically modified plants were grown without any state supervision (For instance, see: Malysh N., 2013). It proves a territorial scope of patent protection: "If a gene has been patented in a country, it is legal to use the gene in countries where a patent has not been granted. However, the patentee could bar the import of products made with processes that would have violated a patent had the processes been conducted in the importing country" (Consultative Group on International Agricultural Research, 1992: 25; see also: Correa C.M., 1996; Tvedt M.W. & Finckenhagen M., 2008). The import ban for GMPs that are recognized to be safe, does not apply in Ukraine. In fact, this has resulted in inclusion in GR management regulations of clauses which are equivalent to precautionary principle. Overall, precautionary principle could reduce incentives for inventors to work on GMPs and act as a barrier for IPR's development. At the same time, such complicated task for scientists, as abiding the precautionary principle in genetic engineering helps to get safer results. i.e encourages research and testing of GMP's before commercial use.

6.2. Stakeholders involved in genetic resource management

Understanding the legal regime of GRs requires identification of the stakeholders who influence GR policy and participate in genetic engineering. Understanding the preferences, interests and values of stakeholders helps identify the role of GRs for society, and brings hope for institutional changes needed to benefit both people and the environment.

Development of TRIPS and CBD influence access to GRs as common-pool resources. Here, questions about social cohesion of agents and cooperative/incooperative behavior appear. Arild Vatn clearly described this case as follows: "Countries will not sign if the convention or

treaty does not offer them net gains. This implies a systematic tendency by those dominantly causing a global environmental problem not to ratify an agreement, since they will often be worse off after a regulation than before… Furthermore, when a treaty is signed, the parties may treat it strategically – that is, not comply if the control system is weak. And again, due to the lack of an international policing and court system, both the possibilities and the temptations are great" (Vatn A., 2005: 288-289). Such behavior of political agents is proven by the example of the USA that did not take obligations under CBD. Though the USA did not sign the CBD, it could participate in appropriate relations. In addition, discussion about revision the TRIPS has been initiated in 90's, where: "the US claimed that the exceptions from patentability in the current agreement should be removed. They were unnecessary and the US already treated plants and animals in the same way as micro-organisms" (Vatn A., 2005: 291). Implementation of the rules of TRIPS and CBD into the national legislation of Ukraine shows cooperative behaviour, but the national legal regime of GRs still needs to be improved.

The primary stakeholder of IPRs in Ukraine is an individual or the employer of the author of the object of intellectual property in relation with his/her official duties. Legal entities may also acquire primary IPRs by force of law. *The derived stakeholder of IPRs in Ukraine* are represented by the successors, which obtained the right by force of law, contract or by inheritance.

A foreigner, foreign entity (established according to the law of Ukraine), and stateless person have the same rights as Ukrainian citizens. Furthermore, Art. 77 of the Law of Ukraine "On Private International Law" (2005) establishes that accommodation of disputes on IPRs is exercised exclusively by the commercial courts of Ukraine, independent of the legal status of stakeholder.

Trying to classify stakeholders who could obtain IPRs to variety of plants and animal breeds (e.g., pedigree factory, pedigree reproducer, and pedigree bird producer), legislators took into account criteria, peculiar to the economic, social, and ecological aspects of appropriate production (Order of Ministry of Agrarian Policy and Food of Ukraine of July 17, 2001 No. 215/66). For instance, "the status of the subjects of pedigree work at livestock breeding is defined according to the area of focus and the indicators of their production and commercial operations, and compliance with the requirements to pedigree (genetic) resources" (Clause 1.3

of Order of the Ministry of Agrarian Policy and Food of Ukraine, 2001). An appropriate status of the stakeholder, who is practicing the pedigree work, is designated according to the results of the state attestation and re-attestation, made by the Ministry of Agrarian Policy and Food of Ukraine (Clauses 1.2., 1.3. of Order of the Ministry of Agrarian Policy and Food of Ukraine, 2001). Finally, these stakeholders should be registered in the State Register of the stakeholders of Pedigree in Livestock Breeding, according to Order of the Ministry of Agrarian Policy and Food of Ukraine of June 13, 2012 No.358.

One of the key persons in communication between the author (breeder), and the user, and the state is a representative on the IPRs. S/he has special legal status, identified by the Decree of the Cabinet of Ministers of Ukraine "The Provisions on the Representatives on the Intellectual Property Rights (Patent Attorneys)" of August 10, 1994 No.545. Clause 1(2) of the given Decree states that: "This provision does not apply to representatives on intellectual property rights to plant varieties". Their activity is regulated by the Decree of the Cabinet of Ministers of Ukraine "The Provisions on the Representatives on the Intellectual Property Rights to Plant Varieties" of August 19, 2002 No.1183.

The representatives of the IPRs act on behalf of the authors (breeder), the applicants (people who filed an application for a plant variety, animal breed or invention) and the patent holder/owner of variety (Clause 1 of Resolution on the Representatives Regarding Intellectual Property Rights (Patent Agents) of August 10, 1994 No.545; Clause 1 of Provisions on the Representatives on Intellectual Property Rights to Plant Varieties of August 19, 2002 No.1183). They "represent the interests of aforementioned people towards the executive authorities, courts, banks as well as with other individuals and legal entities" (Clause 2 of the Provisions on the Representatives on Intellectual Property Rights to Plant Varieties, 2002). In whole, they give advice and services regarding the protection of IPRs to GMPs.

The representative can be a person who satisfies the following requirements: 1) s/he should live permanently in Ukraine; 2) s/he should have higher education relevant for the given field; 3) s/he should have not less than 5 years' experience in the field of the protection of the IPRs/the rights to plant varieties; 4) s/he should pass the appropriate exams, and to have a certificate of the representative on the IPRs / the IPRS to plant varieties (Clause 3 of the Provisions on the Representatives on the Intellectual Property Rights to Plant Varieties; Clause 3 of the Provisions on the Representatives on the Intellectual Property Rights). To

reduce the risk of corruption, legislators foresee that the state system's representative cannot have a title of the above mentioned representative (Clause 4 of Provisions on the Representatives on Intellectual Property Rights to Plant Varieties, 2002) in private cases.

The Executive Authorities of Ukraine that control and regulate GMP's issues are the following:

1) Cabinet of Ministers of Ukraine, particularly Prime-Minister of Ukraine;
2) Ministry of Education and Science of Ukraine;
3) Ministry of Health Security of Ukraine;
4) Ministry of Ecology and Natural Resources of Ukraine;
5) Ministry of Agrarian Policy and Food of Ukraine;
6) Ministry of Economic Development and Trade of Ukraine;
7) Ministry of Labour and Social Policy of Ukraine.

The key ministries are represented in addition by regional (oblast) boards and specialized departments (for ecological control, inspection, etc.). The above mentioned ministries work on the ecological, economic or social constituent of sustainable development. Unfortunately, their functioning could be characterized as unpredictable. Their names, functions, and staff have been changed many times (for instance, the Ministry of Ecology and Natural Resources of Ukraine is based on the former Ministry of Environmental Protection of Ukraine; the Ministry of Agrarian Policy and Food of Ukraine is based on the former Ministry of Agrarian Policy of Ukraine from December 9, 2010 (see: Decree of the President of Ukraine of December 9, 2010 No. 1085/2010). This situation does not promote either sustainable development or integration into the EU, nor GR management development.

General issues on the IPRs are served by *the State Intellectual Property Service of Ukraine,* established according to the Decree of the President of Ukraine "On Ratification of Regulations on State Intellectual Property Service of Ukraine" of April 8, 2011 No. 436/2011. Most of the duties for ensuring and providing IPRs to GMPs belongs to the Derzhvetphytosluzhba of Ukraine (the name is translated in English as *the State Veterinarian and Phytosanitary Service* under the Ministry of Agrarian Policy and Food of Ukraine; hereinafter - SVPS) and partly the State Intellectual Property Service of Ukraine (which is served under the Cabinet of Ministers of Ukraine and coordinated through the Minister of Economic Development and Trade of Ukraine; see: Decree the President of Ukraine "On approval of the State Intellectual Property Service of Ukraine's Statute" of April 8, 2011 No.

436/2011). The SVPS of Ukraine ensures the implementation of state policy in the field of veterinary medicine (particularly, a state supervision (control) for pedigree in livestock breeding), food safety, and protection of plants (See Appendix 7; Provisions on the State Veterinarian and Phytosanitary Service of Ukraine approved by the Order of the President of Ukraine of April 13, 2011 No.464/2011).

Despite the variation of the executive authorities' functions regarding biotechnology, the state has a key role uniting and coordinating stakeholders in GR management: "The state and its government, executive bodies and legislative authorities must create conditions, which will enable improvement of potential and, which is even more important, maximize return. The state shall become a direct guide of the innovative development, customer and manager of the research and designs in the most popular direction of scientific and technical progress" (Preamble of Letter of the President of Ukraine to the Parliament of Ukraine of April 30, 2002). Innovative policy needs to involve, in particular, the modern organizational system of patenting and information management with well developed search and reference mechanisms, access to information on patented genetic technologies in the world.

The Ukrainian legislation established a set of rules about access to information on GMPs. Art. 25 of the Law of Ukraine "On Environmental Protection" (1991) introduced obligatory reporting on any activity with GMOs. Art. 20 of the Law of Ukraine "On State Biosafety System for Developing, Testing, Transportation and Use of Genetically Modified Organisms" (2007), guarantees free access to this kind of information for the citizens. Moreover, according to Art. 14 of the Law "On the State Biosafety System for Developing, Testing, Transportation and Use of Genetically Modified Organisms" of May 31, 2007 No.1103-V, registry of GMO and GMPs shall be published on the web site of responsible central authority and media. Information and description of a plant variety entered in the Register of Varieties and Register of Patents shall be published in official periodical issue of an authorized agency (Art. 34 of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993).

The Golden Rule, "whoever has the gold (GRs in our case) makes the rule", cannot be applied in this case. Such situation breeds many issues, like distribution of costs and benefits. A weak group of stakeholders should loudly pronounce their interests during harmonization of international patent system for GRs. Particularly, if focus is on establishment of legal regime of GRs at the international level, the developing states should be careful in the process of

establishing World Patent System, as mentioned in the works of Morten W. Tvedt (2005, 2007, 2010), and to stand for their interests. Otherwise, worldwide patent could be a powerful tool to put developing countries into deeper poverty and famine. Researcher's interests should also be protected to ensure progress in the development of society. Thomas Cottier (1998) also supported international approach to the patenting of GMAPs: "Rights in a country of origin are of little value if they do not extend to major markets where derived and patented products will be marketed. True, an exclusively international approach may take longer to build and may need more capacity building than a purely national approach… National or international registration does not make a big difference in the electronic age… truly global intellectual property rights system, independent of national legislation and entitlement." (Cottier, T. 1998: 579-580). National legislation should take into consideration pecularities of the legal system and values of certain society. Overall, institutional changes of legal regime of GRs should be made, taking into account differences and peculiarities of stakeholders at the international and national levels.

Chapter 7

LEGAL MECHANISMS

The value of intellectual property for society is determined by its developmental and technological objectives. This has become an issue for protection at the national level. According to Appendix 1C of TRIPS, IPR's are covered by private rights. IPRs to GMPs and IPRs to variety of plants (similar to PBRs in the meaning of Ukrainian law) and animal breeds correlate as general and particular. They have a common legal terminology, but the latter has special legal regulation, which takes into account biological features of the IPR's object and peculiarities of research work in the field.

The characteristics of patenting as legal mechanism of protection of IPRs to GMAPs is explored in this chapter. Understanding the need for institutional changes to IPRs to GMPs in Ukraine demands exploration of the legal rules for its application, conditions for its validity, obligations and limitations of the IPRs to GMPs, crimes and punishment, as established in Ukrainian legislation. As a result, issues on development of GR management in Ukraine can be identified and discussed further.

7.1. Intellectual property rights to genetically modified agricultural products

Producer's choice of mechanism for control and ownership over GMPs depends, first of all, on profitability of the product. Mechanisms of protection of IPR's to GMPs are applied for ensuring ownership through prohibition by patent holder/owner of varieties to use the GMAPs in order to replant, reproduce variety/breed or to use name of patent holder/owner.

As it is stated in Art. 27(3-b) of TRIPS, plant varieties could be protected in three ways: 1) by patents; 2) by an effective *sui generis* system (a system of its own kind, and unique, which establishes an alternative to patents for plant varieties); 3) by any combination thereof. More extensive protection of IPR's could be established in law of the Members, but not contrary to

the provisions of TRIPS. Members make choice on the appropriate method of protection of IPRs to plant varieties taking into account their own legal system and practice (see: Art. 1 of TRIPS). In turn, Art. 15(2) of the Law of Ukraine «On Protection of Rights to Plant Varieties» (1993) established the general rule: "Acquisition of rights to plant varieties abroad shall be performed irrespective of acquisition of such rights in Ukraine".

IPRs to the GMAPs are classified in the Ukrainian law by the following types:

1) personal non-proprietary intellectual property rights to the variety of plants, animal breed evidenced by the state registration (hereafter – "authorship rights");
2) proprietary intellectual property rights to the variety of plants, animal breed evidenced by the patent;
3) proprietary intellectual property rights to disseminate the variety of plants, animal breed evidenced by the state registration (see Appendix 8).

Generally speaking, *IPRs to GMAPs* are the rights of a patent holder to use the object and a right to permit (with certain conditions and limitations) or ban use of this object by other people (Art. 39 of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993; Art. 426(3) of the CCU). Such provisions of Ukrainian law respond to Art. 28 of TRIPS about exclusive rights of patent owner. Owner of the object of IPRs or his/her legal successor (hereinafter – licensor) can completely or partially transfer the right to use the GMP to any other individual (hereinafter – licensee) under license agreement (contract of licence). Similar rule is contained in Art. 28(2) of TRIPS. Contract of the transfer of the property rights to GMP and contracts of transfer of the rights to use of the GMP could be made over the period of patent validity and should be registered at the authority, such as the State Service for Protection of Rights to Plant Varieties of the Ministry of Agrarian Policy of Ukraine (hereinafter – SSPRPV) (Clauses 1.1., 1.4. of Order of the Ministry of Agrarian Policy of Ukraine of July 21, 2003 No.244).

Difficulties in patenting plant varieties and animal breeds include; long delay in registration, and complicated patent procedure (especially as regards the object's expert examination). The right holder has the state protection of his rights in both cases (state registration and patenting), but the state registration of IPRs is cheaper, more efficient and easier than patenting in most cases.

It follows from the above that three types of IPRs to GMPs have been established in Ukraine: authorship rights, proprietary IPRs evidenced by patents and by state registration. To implement the provisions of TRIPS and CBD into the national legal system, Ukraine also established *sui generis* system. Patenting and registration of IPRs to plant varieties are practiced simultaneously. Though such patenting and registration give a different scope of rights and obligations to the stakeholders, they also include a variety of mechanisms of IPRs protection.

Effect of IPRs to GMPs is determined by the conditions and terms of their *validity.* Ukraine has a big list of *the documents which certify the IPRs and grant the permission to use the object* of the intellectual property. It includes the following:

- Patent (declarative patent) – for inventions, plant varieties, breeds of animals;
- contract on creation by the order and further use of the object of the intellectual property right;
- contract of transferring exclusive intellectual property rights;
- contract of commercial concession;
- technology transfer agreement ;
- extract from correspondent state registers;
- other contracts regarding disposal of the intellectual property rights (Clause 25 of National Standard No.4 "Evaluation of Intellectual Property Rights", 2007).

Above mentioned documents shall be affirmed during the examination of the object of the IPRs in order to identify its availability. Particularly, the authorized person ascertains the availability of material object, presence of the above mentioned documents, and the fact of granting a permission to use an object of the IPRs.

Acquisition of the IPRs to an invention shall be witnessed by the patent. At the same time, proprietary intellectual property rights to an invention shall belong to the holder of the respective patent, unless otherwise established by the agreement or the law (Articles 462 (2), 467 (2) of CCU). According to Art. 462 (2) of CCU, "the scope of legal protection shall be determined by the formula of the invention".

In whole, there are two documants and one juridical act which help to fulfill functions of the authorship: state protection documents (patents, certificates) or licenses granted by the patentee, or implementation (introduction) of the innovations (Art. 14 (1) of the Law of

Ukraine "On Innovative Activity", 2002). The difference between patent and certificate is described in the following statement: "Certificate on authorship to a plant variety affirms personal non-property intellectual rights to plant varieties" (Art.10(2) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993). Patent is a protective document certifying the IPRs to the definite object (Art.10(3) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993).

"Some developing countries oppose any form of intellectual property on genetic material. Even after complying with the TRIPS agreement by legislating some form of plant breeders´ rights protection, many still oppose patenting of plant material including genes" (Barton & Siebeck, 1994: 41). Countries do this mainly on political grounds, to secure their national interests. As Ronan Kennedy (2006) noticed: "Patents may limit the freedom of developing countries, because they are predominantly held by developed countries, and thus the former should be entitled to levels of access, perhaps through compulsory licenses, for the benefit of their own plant GRs" (p. 6). India, Thailand, and Columbia have already begun devising intellectual property systems that are friendlier to traditional farmers, while Argentina, Chile, and Uruguay have adopted PBR systems (see: Venbrux G.K., 2006: 23-24). Ukraine allows registration of IPRs to plant varieties/animal breeds. It does not have norms which would prohibit patenting of genes in a direct way; however, there are no rules, which would allow it.

Unlike physical property, IPRs are temporary. Articles 465, 488 of CCU have the general rule that proprietary IPRs to an invention are valid since the date following the date of their state registration. Analogous rule applies to the contract for property alienation (see: Art. 334(4) of CCU). Different terms of validity are established for exclusive proprietary IPRs.

Similar to Art. 33 of TRIPS, validity of exclusive proprietary IPRs *to an invention* shall terminate in 20 years counted from the date of the submission of application for registration of an invention. This term can be extended per the established procedure with respect to the invention the use thereof requiring special examinations and official permit (Art. 465 (3) of CCU). Validity of the exclusive proprietary IPRs *to the variety of plants, animal breed* shall be terminated in 30 years and with respect to trees and grapes – 35 years counted from January 1st of the year following the year of the state registration of these rights (Art. 488 (3) of CCU).

In addition, it is worth mentioning the *special status of Soviet patents,* underlined in Art. 58 of the Law of Ukraine "On Protection of Rights to Plant Varieties" (1993): "In Ukraine valid patents to plant varieties issued in accordance with the legislation being effective before the current Law entered into force have the same legal status as the patents issued according to this Law". The same rule applies to other objects of IPRs protected by Soviet patents in Ukraine.

To be precise, IPRs to GMAPs in Ukraine come into force after filing of an application, examination, patent research and state registration of the rights by state authority, like the SSPRPV (Clause 1.1. of Order of the Ministry of Agrarian Policy in Ukraine of April 26, 2007 No.287; Clause 1.1. of Order of the Ministry of Agrarian Policy of Ukraine of May 28, 2003 No.151; Articles 10 (5), 15(1) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993). In addition, depositing the organism's strain is required. The three legally recognized depositories, as of writing this thesis are: D. K. Zabolotny Institute of Microbiology and Virology of the National Academy of Sciences of Ukraine, Kyiv Research Institute of Epidemiology and Infectious Diseases, Kyiv branch of the State Scientific-Research Control Institute of Veterinary Medicinal Products and Feed Additives of the Ministry of Agriculture of Ukraine (Order of the Cabinet of Ministers of Ukraine of October 12, 1994 No.705).

The motivation of researchers to work on the object of the IPRs depends on the fair remuneration for their work, compensation of expenses, and opportunity to profit from its use over time, recognition and appraisal by society of their achievemnts. Values of GMPs partly could be determined by "the long-term investments into the objects of economic activities aimed at the receipt of income (profit) or achievement of other social effects" (Art. 326(1) of ECU). It is encompassed by the royalty - authorship fees for use of the IPR object. Proper function of the royalty collection mechanism serves as a basis for stimulation of the implementation of genetic engineering in Ukraine.

"New varieties of plants are often sold without license agreements, which prevent distribution and production of high-yield varieties of crops. Ukrainian plant breeders complain that it is hard to receive authorship fees for their work while agrarian manufacturers (e.g., farmers, seed companies – *O.Ch.*) are made to buy sowing material abroad" (Lutsenko I., 2013). Ukraine has low level of adjustment to the world practice of the protection of plant/animal

breeder's achievements now. As a result, breeding by Ukrainian scientists is not as active as it was in the Soviet time.

Payment of remuneration to the authors is regulated by Decrees of the Cabinet of Ministers of Ukraine of May 22, 2013 No.351, and of June 4, 2008 No.520. In particular, Clause 3 of Order of the Ministry of Agrarian Policy and Food of Ukraine of August 16, 2013 No.503, establishes the following: "Payment of fees to an author for creation of the varieties of plants should be in the amount not less than 5 percent from the average personal income, received by an employer (owner of the variety) for using this variety (for a period of use of this variety), and regarding trees, bushes and grapes it shall be not less than 8 percent". The average personal income constitutes 3500 UAH in 2014-2015 ("General amount of income by the regions of Ukraine", n.d.).

Property rights could serve as an input in mutual activity. In particular, it can be *an asset contributed to the authorized capital* (authorized fund of an enterprise or legal entity), a subject of a collateral agreement or other obligations, or part of other business activity, which is not forbidden by the law (Art. 39(5) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993; Art. 424 (3) of CCU; Articles 86(1), 156 (5) of ECU). For example, Art. 156 (5) of ECU specifies: "A holder of the patent may transfer his/her rights to use an invention, utility model or industrial design as a contribution to the authorized fund of an enterprise". Thus, the property rights (including proprietary rights to the intellectual property) could serve as the contributions of members and founders into their business.

Legislators also tried to settle a principle regarding justice and fairness in the legal regime of GR management. They foresaw that authors get royalty during the term of IPR validity, but afterwards people get free access to the object of the IPRs. In case of expiration of the period of validity of intellectual proprietary rights to a plant variety or invention and in case of their early termination or expropriation, the respective object passes to public domain. It could be used freely and at no cost by everyone (Art. 41 (3) of the Law of Ukraine"On Protection of Rights to Plant Varieties", 1992; Art.467(1) of CCU).

7.2. Obligations arising from Intellectual property rights

An author (patent holder, licensor) has both rights and obligations resulting from the obtainment of intellectual property. According to Art. 174 (1) of ECU, *economic obligations* may arise "as a result of creation of the objects of intellectual property and other actions of entities, as well as a result of events with which the law associates occurrence of legal effects in the area of economic activities". One of the obligations of the patent holder is to pay a fee for protection of the IPR object and for maintenance of validity of the proprietary rights. This fee is determined and collected by the Cabinet of Ministers of Ukraine. For instance, fees for actions related to the protection of the IPRs hold 45 basic positions. Extra charge is collected for each item in every additional action (for example, for filing of application (international application) for registration of an invention (utility model), which formula contains more than three items) (Order of the Cabinet of Ministers of Ukraine of December 23, 2004 No.1716).

Such broad spectrum of fees for managing IPRs with payments for additional actions stimulates stakeholders to be strategic and to think ahead how to manage IPRs and what to put in the application. Making changes to the application will cost extra fees for stakeholders. Such an approach to the registration of IPRs helps to save resources (time, labour and materials, including paper). Likewise, it facilitates an evolvement of bureaucracy, puts extra costs on stakeholders, discourages them, and reduces quantity of the IPR's registration. In whole, analyzing IPRs to GMPs, Thomas Cottier (1998) noted: "The very concept of IPRs, however, does not preclude introduction of feasible systems that are cheap and simple. Such systems exist. They are often called petty patents, and complement the more sophisticated patent system designed for industrial purposes. Besides, the complex system of the European Patent Convention, Switzerland, for example, relies upon a national patent system, which is cheap and simple – mainly by way of the fact that since 1978 novelty is no longer examined at the stage of examination and registration. Such questions are left to courts only in the case that patents are being challenged. Interestingly, these patents do not fare worse than patents which had been examined for novelty at the registration stage." (pp. 570-571). Taking into account socio-economic development of Ukraine, such proposal is questionable. The reason for this is analyzed hereafter.

One of the important obligations of stakeholders in GR management is to provide information about conducted activity and product. So, Hamdallah Zedan (2005) summarized experience of different countries in this field and pointed out: "Denmark incorporated a new provision in its Patent Law that requires patent applicants to provide information on the origin of the genetic resources used in the invention for which a patent is sought. In cases of non-compliance, no sanctions are provided in the patent system; however, under criminal law, sanctions are established for the provision of false information to public authorities." (p. 201). Ukrainian law has a requirement regarding provision of information on the origin of GRs, but it does not establish criminal responsibility for the provision of false information. It is in the administrative process that the quality of the provided information will be evaluated and the issue of liability will be resolved.

A patent validity creates obligations for a patent holder. Patent holder should honestly use his/her property right to a variety (Art. 48(1) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993). In order to ensure preservance of the criteria of difference, homogeneity and stability by variety (same as criteria NDUS for the PBRs; Art. 11(2) of the Law of Ukraine "On Protection of Rights to Plant Variety", 1993), a patent holder shall provide, upon request by the authorized agency, protected information, documents, materials, samples, or its derivatives within deadline. According to Art. 48(3) of the Law of Ukraine "On Protection of Rights to Plant Variety" (1993), it is done for the purpose of: a) an inspection of storageability of variety; b) an identification and renewal of variety's official sampl c) carrying out of an expert examination in order to compare different varieties". This obligation is related to the responsibility of patent holder to ensure storage of the variety and his/her components (derivatives) during the period of patent validity (Art. 48(2) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993; Clause 4 of Chapter V of Order of the Ministry of Agrarian Policy and Food of Ukraine of August 16, 2013, No.503). Such storage supports the stable seed features existing at the moment of state registration of the variety (Clause 1.1. of Procedure of the Examination of the Storage Ability of Plant Varieties of July 21, 2003). Varieties of all kinds of plants protected with the law, except for trees and bushes for the reason of the peculiarities of their reproduction, are subject to the examination (Clause 1.4. of Procedure of the Examination of the Storage Ability of Plant Varieties, 2003). Conditions of their storage can be inspected by the Ukrainian Institute of the Examination of Plant Varieties and State Inspection on the Protection of the Rights to the Varieties. Two kinds of the inspections could be performed - planned (represented as control after the

registration) and random (represented as supervision after the registration) (Clause 1.2. of Procedure of the Examination of the Storage Ability of Plant Varieties, 2003).

Altogether, the obligations provide functioning of state mechanism of protection of IPRs objects. Thus, legal obligations which arise from IPRs to GMAPs, could be listed as the following: to pay fees, to honestly use property rights, to provide necessary information and materials to authorities, to ensure storage of variety.

Ukrainian law includes also *limitations of property rights* to plant varieties in the form of each person's right to reproduce materials collected for personal needs as a result of growing the variety at his/her own farm (which corresponds to the «Farmers' privilege» in PBRs). One of the important conditions is that this variety should belong to one of the following kinds and varieties that are popular for use on Ukrainian land: Potato (*Solanum tuberosum*); Oats (*Avena sativa L.*); Rye (*Secale cereale L.*), etc. At the same time, such use of plants should not infringe the rights of owners of plant varieties (Clause 1(2) of Conditions of the Legal Interests of the Owner of Plant Varieties of August 19, 2002 No.1183). These conditions extend to the owners of the farms who reproduce collected materials received by growing the protected plant varieties for their own needs. Supervision for attachment to these rules is exercised by the State Veterinary and Phytosanitary Service of Ukraine (Ukrainian – Derzhvetphytoservice) (Clauses 1, 4. of Conditions of the Legal Interests of the Owner of Plant Varieties, 2002).

Terms and conditions of the above mentioned limitations on the legal interests of an owner of plant varieties are defined by the Cabinet of Ministers of Ukraine *under the following principles*:

a) the size of a land plot is not limited;
b) collected material can be used for sowing by an owner of a farm;
c) an owner of small farm does not pay any fees to the owner of plant varieties (hereinafter an owner of a small farm is an owner who harvests from land, whose plot size does not exceed an area needed to produce 92 tons of crops);
d) other farm owners who use the variety shall pay fee to the owner of plant varieties under mutual agreement. The fee shall be less than charge paid in accordance with license agreement for reproduction of the same variety in the same region (Clause 1(3) Conditions of the Legal Interests of the Owner of Plant Varieties, 2002).

Above mentioned limitations shall facilitate well-being and increase the welfare of farmers in Ukraine. Otherwise, introduction of fee for use of patented GMAPs and appropriate sanctions can lead to the following situations: 1) increase of illegal use of patented GMPs (infringements of IPRs); 2) decrease in farmer's income, poor food diversity and starvation (still in recent memory is the famine, "Holodomor", which was partly caused by low level of harvest in Ukraine in 1932-1933); 3) farming, which uses the majority of the Ukrainian agricultural lands, would have less stimuli for plant production.

7.3. Crimes and Punishment

In Ukrainian legislation, infringements of IPRs to GMPs include the following violations:

1) misappropriation of authorship as infringement of personal non-property intellectual rights (including disclaim of this right);
2) immediate perpetration of any actions that require permission of the plant variety patent holder/owner, relatively the IPRs object (Art. 53 the Law of Ukraine "On Protection of Rights to Plant Varieties" (1993); Art. 431 of CCU).

In most cases, stakeholders try to avoid patent infringement by including restrictive covenants in licence agreements. For example, "Monsanto's 2004 US Technology \ Stewardship Agreement (on "Roundup Ready" soybean seeds – *O.Ch.*) provides the purchaser with a limited licence to purchase and plant seed containing Monsanto technologies… In particular, this seed may only be used for planting a single commercial crop" (Hubicki S. & Sherman B., 2005: 270). The main aim of application of restrictive covenants is to reduce costs of the IPRs protection through notification to the user of patented object about their responsibility. Unfortunately, such methods are not always effective in protection of IPRs. Cases of "bad stewards" who fail to comply with the terms of patent licences arise periodically in the news. Companies may be reluctant to invest in research of new GMPs in such situations. As a solution to this problem, the above mentioned Technology Protection System has been developed.

One of the functions of responsibility for violations of legal requirements is to ensure effectiveness of legal norms. According to Ukrainian law, four types of legal responsibility

may be applied: disciplinary, administrative, criminal and property responsibility (wich involves compensation for damages caused by the violation). Regulations on legal responsibility are codified in the special legal acts: in the Code of Ukraine on Administrative Offences of December 7, 1984 (on administrative responsibility), the Criminal Code of Ukraine of April 5, 2001 (on criminal responsibility), the Labour Code of Ukraine of December 10, 1971 (on disciplinary responsibility), the Civil Code of Ukraine of January 16, 2003 (on property responsibility).

Ukrainian law established the same rule as does Art. 34 of TRIPS, in particular, that the burden of proof in cases of IPRs rests on the alleged infringer. The defendant has to prove that the process to obtain an identical product is different from the patented process.

Stakeholder, whose IPRs to GMPs are infringed, is entitled to demand:

a) cease of actions which are leading to infringement of his/her rights;
b) compensation of inflicted damages including uncollected incomes;
c) compensation of moral injury;
d) other measures foreseen by the Law for protection of IPRs to GMPs.

A stakeholder who possesses a right to use a GMP by license agreement is entitled to demand renewal of infringed rights of a patent holder. At the same time, an infringer shall cease violating these rights and compensate inflicted damages upon demand by a patent holder (for example, Art.53 of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993; Art. 386(3) of CCU).

The court is entitled to approve the following decisions in such cases:

1) compensation of the moral (non-property) injury;
2) compensation of the damages, caused by infrigment of IPRs; estimation of such damages is regulated by the National Standard No.4 "Appraisal of Intellectual Property Rights" approved by the Order of the Cabinet of Ministers of Ukraine of October 3, 2007 No. 1185. Depending on each individual case, there is a recommendation to use such methodological approaches, as profitability, comparison or consumability (Clause 8 of National Standard No.4, 2007);
3) collection of income received by an infringer as a result of infringing the IPRs including profit lost by patent holder;

4) enforcement of compensation defined by court in the amount from 10 to 50000 minimal wages considering whether infringement was committed intentionally or without intention instead of compensation or income collection;
5) an application of a single monetary penalty instead of reimbursement for losses due to unlawful use of the object of the IPRs. The amount of the penalty shall be established pursuant to the law taking into account the guilt of a person and other circumstances being of vital importance;
6) a cessation of the actions leading to infringement of the IPRs (application of the immediate remedies to prevent infringement of the IPRs and to preserve respective remedies; terminate trespass through the Ukrainian custom borders of goods imported or exported with the violation of the IPRs; withdrawal from civil circulation of goods manufactured or brought into civil circulation as a result of infringement of the IPRs; withdrawal from civil circulation of materials and instruments used mainly to manufacture goods in violation of the IPRs);
7) publication in the mass media of information about infringements of the IPR and the contents of court judgment regarding such infringements (Art.55 (1) Law of Ukraine "On Protection of Rights to Plant Varieties", 1993; Art. 432 of CCU).

The Code of Administrative Offenses of Ukraine (1984) foresees a range of fines, which depend on the peculiarities of the case (See: Appendix 9). In addition, according to Art. 55(2) of the Law of Ukraine "On Protection of Rights to Plant Varieties" (1993) the court is entitled to impose a fine upon the infringer in the amount of 10% of the whole payment awarded by the court in favor of the plaintiff. The fine shall be transferred to the State Budget of Ukraine.

The Ukrainian court is also entitled to make a resolution in certain cases, such as those on the varieties of plants, about:

а) expropriation or confiscation of any material related to the variety and product received from the business trade (material and product of the variety honestly obtained by other means are not subject to expropriation);
б) expropriation or confiscation of any materials or/and equipment which have been used for unlawful manufacture of variety's material (Art.55(3) of the Law of Ukraine "On Protection of Rights to Plant Varieties", 1993).

Measures of legal liability, foreseen in the national legislation, and remedies established in Articles 45, 46 of TRIPS, correspond to the seriousness of the infringement in every single case. The interests of third parties shall be under consideration, too.

Analyses of administrative legislation demonstrates that the administrative procedure is conducted by the authorized people from the authorities, state tax service, by the court or public inspectors on the intellectual property and protection of rights to plant varieties (Clause 2.1. of the Supreme Court of Ukraine Generalization of the legislation of January 1, 2006).

Art. 177 of the Criminal Code of Ukraine (2001) provides for liability for violation of the rights to invention, variety of plants, and innovative proposals. On the subject of guaranteeing fulfillment of the precautionary principle, the Criminal Code of Ukraine (2001) also includes a special chapter "Crimes against the environment" (Art. 236-254). Criminal responsibility for infringement of IPRs to GMPs and improper (or illegal) use of the GMPs incurs punishment in more severe forms. As punishments, there may be applied penalty, deprivation of the right to occupy certain position or to carry out certain activity, confiscation of property, arrest, restriction or imprisonment for a certain term.

Judicial application of patent matters does not have a long tradition in Ukraine, as compared to other countries. For instance, in the USA "the incidence of jury demands in patent cases has grown from about 3% in the late 1960's to more than 50% in recent years… About 60% of patent trials completed in year 2001 were tried by a jury." (Maloney, T. 2005: 391). It could be explained in relation to the amount of patented GMAPs: Ukraine has a small amount of cases in the court due to the small amount of patented objects. In addition, farmers in Ukraine are less wealthy as compared to farmers in developed countries. So, it would be complicated to enforce court decision which involves, for example, financial compensation.

Robert P. Benko (1989) expressed an interesting point of view in relation to the court cases: "Judges and enforcement officials often do not enforce protections which may exist because they believe that restrictive definitions of intellectual property rights will hurt national economies by granting monopolies to foreign nationals." (as cited in Powers M.A., 1993: 117). This is also another reason why Ukraine does not have statistics on the court decisions about IPRs to GMAPs.

In addition to the IPRs infringements, *violation of environmental legal requirements* during operations with GMO is also punishable by the law (see: Art. 68(o) of the Law of Ukraine "On Environmental Protection", 1991; Appendix 5). Due to peculiarities of GMAPs, it is difficult to prove a link between the right to live in a healthy environment and harmful influence of the GMAPs. So, some cases are not recognized as admissible by court, like case *Brun v France,* (2006): "In the present case, the Committee notes that the author's arguments… refer to the dangers allegedly stemming from the use of GMOs and observes that the facts of the case do not show that the position of the State party on the cultivation of transgenic plants in the open field represents, in respect of the author, an actual violation or an imminent threat of violation of his right to life and his right to privacy, family and home. After considering the arguments and material before it the Committee concludes therefore that the author cannot claim to be a "victim" of a violation of articles 6 (on the inherent right to life – *O.Ch.*) and 17 of the Covenant (the right to privacy – *O.Ch.*) within the meaning of article 1 of the Optional Protocol" (Clause 6.3 of case *Brun v France,* 2006).

Ukrainian law established the right of everyone to require termination of illegal activities that result in destruction, deterioration, or pollution of the environment. Such cases may be decided by court (Art.293(2) of CCU). At the same time, there are fewer chances to violate environmental law, if the GMP is registered and used legally.

Summing up, IPRs to GMAPs in Ukraine have got positive and defensive protection. Positive protection consists in establishment of the IPRs legal mechanism. Defensive protection includes use of legal or other means to prevent certain crimes (mainly, establishment of responsibility and enforcement of law through the court decisions).

Chapter 8

D I S C U S S I O N S

The effectiveness and fairness of protecting IPRs to GMAPs is debated internationally. One of the obstacles to development of the trade regime (TRIPS) is the environmental regime established by the CBD, particularly, the precautionary principle. Co-relation between IPRs and GMPs functions under the influence of the issues which are created at the national level of member-states and contain legal mechanisms for providing the effectiveness of national GR policy.

The institutional structure of IPRs to GMPs got new descriptions by three directors-general: ‘as an “evolutionary burst” in the way intellectual property is being used (by WIPO representative Francis Gurry); a system that needs to be readjusted because of unsustainably high costs, market failure in providing a response to certain types of diseases affecting the poor, and a decline in breakthrough inventions (by WHO representative Margaret Chan); as a system requiring a movement from “coherence” to “convergence” in the way international organizations work together (by WTO representative Pascal Lamy) ‘(WTO, 2013). So, changes in the organization and regulation of GR management are required.

One matter concerns adjustment of the TRIPS and CBD regimes. Establishment of common norms in the field would ensure unique values over GRs. In the author’s opinion, Ukraine has successfully accomplished this task. As it was shown previously, implementation of international agreements into Ukrainian law has been accomplished through establishment of the legal regime of the GRs. Environmental rules are harmonized with the rules on the patenting of GMAPs in Ukraine. At the same time, practical application of its provisions is restricted, first of all, by insufficient infrastructure, underdevelopment of the innovation management system, and its separation from the manufacture.

Another problem lies in the inneffective protection of IPRs to GMAPs. Domestic inventors cannot implement the economic potential of the most of their inventions in Ukraine. As it is

mentioned in Clause 7(4,5) of the Recommendations of Parliamentary Hearings on National Innovative System of Ukraine (2007): "The number of the registered contracts is only 2.2-2.6% of total quantity of patents, which is few times less than in the developed countries. Comparing with 1991, the number of inventors and innovators has decreased by 20 times. There is only small quantity of enterprises engaged in inventive and innovative activity. Ukraine remains substantially behind the developed countries by export-import of technologies". Understanding such dire tendency requires insight onto the social and economic situation in the country and how it influences the development of genetic engineering, how actors' interests are satisfied and what the state does to improve the situation.

"Taking into account world experience, *strategies of innovative development* can be classified in three types:

1) *the strategy of transfer* (use of foreign science and technical potential and its adaptation to the national economy),
2) *the strategy of borrowing* (mastering of the production of high-technology products which are already produced in other countries by applying own cheap labor force and existing science and technical potential),
3) *the strategy of accumulation* (use of domestic science and technical potential, attraction of foreign scientists and designers).

The first and, partially, the second types of the innovative development prevail in Ukraine." (Clause 1(5) of Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007). In spite of possibility to create the national innovative system in Ukraine during 20 years of independence, the system has not been created. Unfortunately, Ukrainian innovative activity is characterized by structural deformity, institutional deficiency, disconformity, and lack of balance in technological, economic, and social aspects.

According to the research of UN at the beginning of XXI century, Ukraine led the world in the number of research workers per capita. The level of enlightenment exceeded the average index of the countries of Eastern Europe and CIS (Preamble, Paragraph 4 of Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007). A high number of research workers does not necessarily mean production of high quality goods. There are observed *the following trends in Ukrainian science:*

1) Aging of scientific staff: old researchers, educated and trained in the Soviet Union, hold leadership positions in most of the research institutes. They have high salary, good social values and families in Ukraine. There is little turnover in this demography. Their numbers are decreasing with each passing year. "Based on mortality rates, Ukraine is among the top ten countries in the world community, and it places 60th in life expectancy. The main reason for deaths in our population are multifactored diseases (cardiovascular, oncological, endocrine, mental, etc), which arise as a result of a combination of heredity, social, and environmental factors. The prevalence of morbidity among the disadvantaged population exceeds by 45.7 percent the analogous indicator among the wealthy" (National Environmental Policy of Ukraine, 2007: 17).

2) Scientific emmigration: Young scientists can migrate to work abroad. There, they have access to modern research equipment, good salary and social wages. This fact is proven by the following: "only 2 per cent of scientific equipment of Ukrainian research and technological institutions corresponds to the level of modern world standards" (Preamble, Paragraph 17 of Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007). "The last inventory, performed according to Order of the Cabinet of Ministers of Ukraine "On the Measures for Strengthening of Physical Infrastructure of Scientific Institutions and Schools of Higher Education" of December 21, 2001 No.591-p, stated that out of 159.7 thousand machines and equipment remained on the Books of inspected organizations, 80.1% operated over 10 years and only 6.4 % operated under 5 years. At the same time according to world standards, the term of operation of scientific equipment shall not exceed 5-7 years" (Clause 5(8) of Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007). In addition, much equipment, which was in good condition after the collapse of the USSR, has disappeared mysteriously from public domain. As to the salary of researchers, Paragraph 28 of Preamble of the Recommendations of Parliamentary Hearings on National Innovative System of Ukraine (2007) notes: "Average monthly salary of scientific workers is still less than the one stipulated by the law because it has to be twice bigger than salary of industrial workers." Overall, such situation proves words of James O. Odek (1994), that: "The issue is not ownership of the gene but possession of the technology to utilize genes in a particular environment." (Odek J.O., 1994: 152).

3) Reduction of number of graduates, willing to work in Ukrainian science: time and energy-consuming scientific job are not commensurately compensated. Brainy young people do not have incentives to work as researchers in Ukraine. Statistics shows: "only 0.6 per cent of general numbers of graduates of establishments of higher education, who receive master and specialist's degree, get a job at scientific organisations" (Preamble, Paragraph 29 of Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007).

Overall, according to Paragraph 19 of the Preamble of the Recommendations of Parliamentary Hearings on National Innovative System of Ukraine (2007): "During 1995-2005 there was a reduction of the number of workers at scientific institutions by 1.7 times (from 293.1 thousand to 173.9 thousand), and the number of science workers increased 1.2 times in social sciences and it has not changed in natural sciences and humanities whereas in technical sciences field this number has decreased by more than two times". Such tendency in science threatens intellectual heritage of Ukrainians. It leads to the losses of scientific schools and the potential research staff. As a result, "innovative processes in Ukraine have not reached sufficient scales and substantial aspect of GDP increase. Science and technical potential of Ukraine is practically excluded from the economic development of the state. Science linkage of industrial production of Ukraine does not exceed 0.3 per cent, which is significantly less than the world's average level. Share of high technology products as percentage of GDP is decreasing. In 1998, this index was 3.1 per cent and in 2004, it declined to 0.7 per cent. Own funds of enterprises are still the main source of financing of innovations. Their share at the total volume of financing constitutes 84.6 percent" (Preamble, Paragraphs 9, 10, 14 of the Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007). At the same time, Art. 17(1) of the Law of Ukraine "On Innovative Activity" (2002), established that the subjects of the innovative activity for implementation of innovative projects can be funded by:

a) providing interest-free loans (on conditions of inflator indexation) of innovative projects of primary priority by funds of the State Budget of Ukraine, budgetary funds of the Autonomy Republic of Crimea and local budgets;

b) partially (up to 50% off) interest-free loans (on conditions of inflator indexation) of innovative projects of primary priority by funds (as above) with conditional attraction of other necessary funds of the project contractor or (and) other subjects of the innovative activity;

c) full or partial compensation of loan interest (as above) paid by the subjects of the

financial and credit institutions to commercial banks and other financial and credit institutions for crediting the innovative projects;

d) issuance of the state guarantees to commercial banks that give credits to carry out the innovative projects of primary importance (to be precise, it means support of the innovative projects aimed at implementation of economic and social policy of the state (Art.329(1) of ECU);

e) property insurance of the innovative projects' implementation by insurance agencies in accordance with the Law of Ukraine "On Insurance" of March 7, 1996, No. 85/96-BP.

Regarding genetic engineering, these legal provisions were not applied in practice. State policy does not stimulate development of science. In particular, the mechanism of organization and use of the industrial funds for research, the extra budget funds, and the investments into innovative branches by banks and other investors are not provided in Ukrainian law.

Another destructive factor for development of biotechnologies in Ukraine is the declarative provisions of law (e.g., state safeguarding and protection of the IPRs, protection against unfair competition in the field of innovative activities, which is all foreseen by Art. 329(1) of ECU). Such guarantee could be realized only through the involvement of the relevant institutions. Since Ukraine has a high level of corruption, legal provisions regarding guarantees are absent.

Each project has its own financing mechanism, depending on its priority and potential results. According to Art. 6(3) of the Law of Ukraine "On Priority Orientations of Innovative Activity in Ukraine" (2011), in order to implement mid-term orientations of the innovative activity, the state takes the following measures:

1) development of the innovative infrastructure (innovative centers, technological parks, scientific parks, technologies, innovative business-incubators, centers of technology transfer, innovative clusters, risky funds etc.);
2) direct budgetary funding and co-funding (Clause 5(6) of the Recommendations of Parliamentary Hearings on National Innovative System of Ukraine (2007) established that: "the State should provide a finance support in the amount up to 30 percent of the project cost whereas the rest of funds shall be provided by an entrepreneur or investor";

3) compensation of interest rates on the credits obtained by market participants from banks;
4) partial compensation of production costs;
5) loans by means of the state budget, credits (loans) and grants of the international financial organizations attracted or guaranteed by the state;
6) government grants from the state budget to local budgets;
7) tax, custom and monetary preferences.

Unfortunately, these legal rules stay declarative. Reorganization of scientific organizations will not help, either. What is needed is stable provision of scientific needs (economic and social).

"Actual financing of scientific and technical activity by the State Budget of Ukraine during last five years does not exceed 0.4% of GDP. According to Chapter 34 of Law of Ukraine "On Science and Technical Activity" of December 13, 1991 No. 1977-XII**,** the rate of financing shall be 1.7%. Specific weight of programme-purposed financing of researches does not exceed 10% of general expenses on science while the law provides for 30%" (Clause 2(4) of the Recommendations of Parliamentary Hearings on National Innovative System of Ukraine, 2007).

Thus, Ukrainian scientific activity is affected by reduction of centralized capital investment and lack of financing of science, aging of workers and equipment, worsening of infrastructure, and lack of material procurement. Absence of science from industry leads to low levels of production efficiency. Such situation significantly affects the national economy resulting in the low level of technology development. Reduction of scientific potential is accompanied by dependence on foreign producers and import, and degrades job market.

To improve the situation with GR management and to use research potential in an efficient way, some institutional changes are necessary in Ukraine. The Ukrainian law, which has implemented many international provisions on the IPRs to GMPs, promotes development of GR management in Ukraine, yet there are enforcement problems. The process is restrained by low level of financing of research and poor social services for scientists in genetic engineering.

C O N C L U S I O N

GRs are a source of conflict between developed and developing countries. Developed countries own capital and technologies for research, production and patenting of GMPs. Developing countries often have only GRs as raw material. This uneven distribution of power is an issue discussed in this thesis together with distribution of rights and opportunities for agents. CBD and TRIPS have been called to regulate the given situation. As a result, there is a conflict between the trade regime and environmental regime, because of the difference in their goals: to regulate international trade (in favour of the strong agents) or to protect human health, biodiversity and the environment.

Differences between CBD and TRIPS regimes reflect the polarity of agent's interests. While the CBD guarantees the agent's rights to access and use GRs, and establish benefit-sharing principle, TRIPS has been guaranteeing to the providing agent property rights to benefit streams from GRs for twenty years (in case of GMPs patenting). The same disparity can be seen in the application of precautionary principle (derived from the CBD/Cartagene Protocol) and burden of proof (derived from the TRIPS). Equality of stakeholders does not exist either de-facto or de-jure. There are different capacities and scope of rights for them to participate in GR management. A right of one agent establishes an obligation for another. The potential opponent of right-holder has fewer possibilities to have benefits, derived from the object of IPRs. Then different situations in GRs regime resulted. Rights established by the CBD interfere with those established by TRIPS. This situation is complicated by the so called "free-rider" problem (see Chapter 6.1., case: *Madagascar vs. Eli Lilly, the USA)*, which demands public action. To minimize conflict, institutional change through a revision of legal rules regarding GRs such as treaty about the World Patent System could be considered.

The author's search of literature and analysis of issues regarding IPRs to GMAPs in Ukraine resulted in the following answers to research questions.

8.1. How were international rules on patenting of GMAPs implemented in Ukraine?

When Ukraine became a member of the WTO on May 16, 2008, it became obliged to implement TRIPS. The main provisions on the IPRs to GMPs are included in the Civil Code

of Ukraine, the Economic Code of Ukraine, and Law of Ukraine "On Protection of Rights to Plant Varieties" of April, 21, 1993 No. 3116-XII.

GRs, as elements of natural resources, located within the boundaries of Ukraine, its continental shelf, exclusive (marine) economic zone are the objects of ownership right of Ukrainian people (Art. 13 of the Constitution of Ukraine, 1996). They are managed by the authorities and local governments on behalf of the state within the limits established by law.

Objects of IPRs could be identified as a result of intellectual and creative work, expressed in an objective form or fixed on a particular physical medium. Art. 420 (1) of CCU specifies that objects of IPRs could be: data compilation (database); scientific discoveries; inventions; plant varieties and animal breeds; etc. This provision gives stakeholders the possibility to choose the mechanisms for protection of IPRs to GMAPs. The same object can be covered by different categories depending on its characteristics and socio-economic functions.

Unlike TRIPS, microorganisms, non-biological and microbiological processes are not mentioned, as eligible for patenting in Ukraine. Since TRIPS has the same legal force as national law, patenting is possible if the aforementioned fit the description of a type of IPRs established in Ukrainian law (scientific discovery, inventions and so on). Definition of scientific discovery as an object for patenting in relation to GRs is absent in Ukrainian legislation. Conditions for patenting of scientific discovery require presence of the invention's elements.

Ukraine has also established *sui generis system* for protecting plant varieties. Both patenting and registration of IPRs to plant varieties are practiced in Ukraine. They provide different scope of rights and obligations for stakeholders. Patenting includes a wider range of rights and obligations. Both patenting and registration of IPRs to plant varieties ensure IPRs' protection.

8.2. How does the precautionary principle influence the implementation of international rules on IPRs to GMAPs at the national level?

National environmental strategy of Ukraine is supposedly aligned with EU strategy. Ukraine began to establish the political and legal institutions for adapting its legislation to the EU

requirements long ago. In addition, according to the UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters from June 25, 1998 (Aarhus Convention), the GMO notification scheme has been developed in Ukraine. Such wide-range of legal regulation of environmental rights could prevent cases, like case *Fredes Gonzalez v. Chile* (2009) on access to information on GMO, which has been recently considered by the Inter-American Commission on Human Rights. State resource management is aimed at protection of the environment in Ukraine: to provide environmental safety, rehabilitation of the environment, and restoration of ecological balance in the ecosystems. The Ukrainian government's recognition of a priority of ecological problems is logical because the problems influence the social activities, human health and interests of future generations. At the same time, however, the system of controlling and monitoring GMP's circulation and the methodology for determining their influence on the environment (including human health) interferes with IPRs to GMPs.

The precautionary principle is a prerequisite for patenting of GMAPs. This results in a mix of law branches regulating GR management in Ukraine (environmental law, civil law and commercial law). Patenting issues are regulated by civil law, while issues on GRs and human health are regulated by environmental law. So, there is a complex mix of legal regulations of GR management. Perhaps, implementation of a single all-encompassing law on GR management would help to systemize legal rules. It would establish a framework with flexible strategies for regulating relations between mankind and nature, considering the specificity of GRs as particles of natural resource, which could be turned into objects of IPRs.

Bringing together normative acts into an ordered system would systemize a large number of legal acts on GRs, and would help to eliminate provisions that duplicate one another and to fill the gaps in law. The complicated synergy of the "environment-health-knowledge" system which is built on a harmony of ecological conditions, human health and science together with technological progress, could be established in the new law on GR management. The basic terminology on GR management also needs to be unified. A national policy on GR management should be built providing information on the GMAPs and economic mechanisms for their development. Furthermore, an easy access and clear interpretations of law would improve fullfilment of human rights, increase the effectiveness of legal education, and enhance researches on GRs.

Ukraine has fulfilled its task on ecologization of economic activities, which was debated at WHO-WIPO-WTO Symposium (July 5, 2013). At the same time, limited information on GRs and lack of financing slow down the development of GR management in Ukraine. Establishment of market economy on the national level with the moral responsibility towards future generations at the core is disputable nowadays. Ecological measures should be considered as a factor for stabilization and economic development, not as obstacles to economic and social development.

8.3. What are the obstacles for development of GMAP's patenting in Ukraine?

Legal regime of IPRs to GMAPs is well-established in Ukraine. Legally, patenting is protected and ensured, but Ukrainian law is mainly declarative and not enforced as regards financing research on GMAPs. Although civil society and market economy are established in Ukraine, poor practical application of laws remains an issue. Administrative and regulatory dysfunction needs to be eliminated in Ukraine first.

Obstacles for development of GMAPs' patenting in Ukraine could be classified into two groups:

1) inefficient work of authorities on patenting issues;
2) absence of drivers for development of GMAPs.

1) Inefficient work of authorities on patenting issues.

Efficiency of national agents is hampered by the following factors.

a) Too broad scope of competence for too many national agents involved in GR management. These agents coordinate, monitor, and examine the activity on GRs. The large number of stakeholders is not a guarantee of effective enforcement of law and state policy because it disperses financial and personnel resources. The concept of public control of GR management in Ukraine could be treated as overdeveloped. Imbalance between functions of authorities is caused by dozens of legal regulations and results in bureaucracy. Plurality of authorities should be adapted to the trade regime of GRs taking into account ecologization of economic activity. In the author's opinion, establishment of one state authority guided from a single center, would be more effective. It would have competence to identify, plan, finance, and control the fulfillment of necessary investment programs on GRs taking into account both natural resource management and environmental protection. At the same time, such authority

could be easily influenced by the corruption as observed elsewhere in that society when power is concentrated in one body.

Corruption is rampant in governance systems in third world countries. Stable social development could help to reduce corruption. Social development could benefit through development of knowledge-based industry, like GR management.

b) Lack of competence. State authorities can make political decision, but, frequently, their functions cannot be performed for professional and psychological reasons. Unstable political situation causes frequent rotations in the authorities, where people with special education and skills (like biological/ecological education) are on great demand. Thus, GR management in Ukraine should be improved on the basis of scientific validity, consistency, and stability.

2) Absence of drivers for development of GMAPs.

Ukraine inherited science (scientific potential of people) and technological base for production (infrastructure) from the USSR. Unfortunately, infrastructure was partly stolen and the technological base did not get renewal. Incentives or possibilities for investments in genetic engineering during 1990-2000's were not foreseen. As a result, the infrastructure for research on GRs has been destroyed and new base has not been created.

Mechanisms of implementation of state investment programs are inadequate for the demands of modern market and science. Although those programs include investment from the private sector and municipalities, they do not stimulate potential investors. National economic mechanism should be based on a combination of instruments, which would economically encourage agents to conduct research on GMAPs and to patent them in Ukraine. In particular, technical aid (international and national) and foreign investors should be eligible to fund joint projects on GRs, too.

Establishment of opportunities for introducing technological innovations developed by domestic scientists, wich are promising from an ecological and economic point of view, should be the primary task of the state policy in Ukraine. GR policy requires an effective economic mechanism to stimulate development. To become a part of the national economy, the GR policy should be pursuited in compliance with the international obligations of Ukraine

and the EU principles. Modernization of economic mechanism for financing projects to develop GMAPs could be done through precise regulation in law issues on: credit privileges (granting interest-free or soft loans), taxation (reduction in taxes, flexible taxation or clearing them), and differentiation of pricing, for example, on technological base. Such fiscal payments generate revenue for the national government. Reduction of revenue would be compensated by income from patented GMPs.

Implementation of such economic mechanism would decrease expenses of stakeholders. Modernization of the economic mechanism for GR management would further state development, create jobs and ensure socio-economic prosperity. It is easier to support present infrastructure and people than rebuild all from the beginning. Political failure to support GR management in Ukraine affects innovative development of the country.

Thus, Ukrainian law is enforced in terms of environmental regime of CBD, where no financial needs are on the demand. State authorities do their job very well and keep precautionary principle at the initial stages of GR management. Generally speaking, implementation of precautionary principle in Ukraine favours the prosperity of corruption and bureaucracy with its wide net of authorities and duplication of competence. At the same time, Ukrainian legislation on providing financing and stimulus for producing patentable GMAPs is declarative. This keeps GR management away from development in Ukraine.

REFERENCES

Abeba, T.G. (2009). Material Transfer Agreements on Teff and Vernonia – Ethiopian plant genetic resources. *Journal of Politics and Law*. 2(4), 77-89.

Agreement for Partnership and Cooperation between the European Communities and their Member States, and Ukraine (June 14, 1994; came into force on March 1, 1998), ratified by Law of Ukraine No.237/94-VR of November 10, 1994. Retrieved from: www.rada.gov.ua (in Ukrainian).

Andersen, R. (2005, Dcember). *The history of farmers' rights: A guide to central documents and literature*. FNI Report 8/2005. (Lysaker, Norway: Fridtjof Nansens Institutt). Retrieved from: http://www.fni.no/doc%26pdf/fni-r0805.pdf

American Enterprise Institute for Public Policy Research. (1987). *Protecting intellectual property rights, issues and controversies*. Washington, D.C.: Benko, R.P. (as cited in in Powers M.A., 1993).

Aoki, K. (2009). Free seeds, not free beer: Participatory plant breeding, open source seeds, and acknowledging user innovation in agriculture. *Fordham Law Review*, 77, 2275 – 2310.

Baba, E.J. (2003). From conflict to confluence: protection of databases containing genetic information. *Syracuse Journal of International Law and Commerce*, 30(1), 121-150.

Barton, J.H. & Siebeck, W.E. (1994). *Material Transfer Agreements in genetic resources exchange - the case of the international agricultural research centers*. *Issues in Genetic Resources*, 1, Retrieved from: http://www.bioversityinternational.org/e-library/publications/detail/material-transfer-agreements-in-genetic-resources-exchange/

Bates, K. (2007). A penny for your thoughts: private and collective contracting for traditional medicinal knowledge kodeled on bioprospecting contracts in Costa Rica. *Georgia Law Review*, 41(3), 961- 1011.

Berg Trygve (2012). *Lectures on Genetic Policy and Law*. Norwegian University of Life Sciences, NORAGRIC.

Beslier, S. (2009). The protection and sustainable exploitation of genetic resources of the High Seas from the European Union's perspective. *The InternationaJ ournal of Marine and Coastal Law*, 24, 333-341.

Blakeney, M. (2000). Access to genetic resources: some concerns. *International Intellectual Property Law & Policy*, 4, 61-1 – 61-11.

Braithwaite, J. & Drahos, P. (2000). *Global business regulation*, Cambridge, UK: Cambridge University Press.

Bryman, A. (2008). *Social Research Methods* (3rd ed.). Oxford ; New York : Oxford University Press.

Bugera, S. (2012). Legal regulation of quality of agricultural products in accordance with EU requirements. *Public Law*, 1(5), 128-132 (in Ukrainian).

Bunning, S.E. & Hill, C.L.M. (1996). *Farmers rights in the conservation and use of plant genetic resources: A gender perspective*. Rome: FAO. Retrieved from: http://www.fao.org/docrep/x0255e/x0255e03.htm

Carlson, J.C. (1996). Strengthening the property-rights regime for plant genetic resources: the role of the World Bank. *Transnational law & Contemporary problems*, 6, 91-122.

Case *Brun v. France* [2006]. CCPR/C/88/D/1453/2006. 23 November 2006. Retrieved from: http://webcache.googleusercontent.com/search?q=cache:aZXsB-zaOrEJ:www1.umn.edu/humanrts/undocs/1453-2006.html+&cd=1&hl=en&ct=clnk&gl=no

Case *Diamond v. Chakrabarty* [1980]. 447 U.S. 303 No. 79-136. June 16, 1980. Retrieved from: https://supreme.justia.com/cases/federal/us/447/303/case.html

Case *Ex Parte Hibberd* [1985]. 227 U.S.P.Q. 443, 444. September 18, 1985. Retrieved from: http://www.iplawusa.com/resources/227_USPQ_443.pdf

Case *Fredes Gonzalez v. Chile* [2009]. Retrieved from: http://www.cidh.oas.org/annualrep/2009eng/Chile406.03eng.htm#_ftn1

Case *Harvard College v Canada (Commissioner of Patents)* [2002]. SCC 76. Retrieved from: https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2019/index.do

Case *Monsanto Canada Inc. vs. Schmeiser* [2004]. 1 S.C.R. 902, 2004 SCC 34. Retrieved from: http://scc-csc.lexum.com/scc-csc/scc-csc/en/item/2147/index.do

Case *Moore v. Regents of the University of California* [1990]. July 9, 1990. Retrieved from: http://www.eejlaw.com/materials/Moore_v_Regents_T08.pdf

CGIAR. (1994). *International experts debate patents and biodiversity issues: CGIAR highlights*. Washington, D.C.: CGIAR. Retrieved from: http://www.worldbank.org/html/cgiar/newsletter/Feb94/v0106406.html

Chander, A. & Sunder, M. (2007). Is Nozick kicking Rawls's ass? Intellectual property and social justice. *UC Davis Law Review*, 40, 563-579.

Civil Code of Ukraine, established by Law of Ukraine of January 16, 2003 No.435-I (effective as of January 1, 2004). Retrieved from: www.rada.gov.ua (in Ukrainian).

Code of Ukraine on Administrative Offenses, established by Law of Ukraine of December 7, 1984 No.8073-X. Retrieved from: www.rada.gov.ua (in Ukrainian).

Colston, C. (2002). Challenges to information retrieval - a global solution? *International Journal of Law and Information Technology*, 10(3), 294-326.

Colston C., (2007). Protecting databases - a call for regulation. *Denning Law Journal*, 19, 85-121.

Conditions of the Legal Interests of the Owner of Plant Varieties in Case of the Limitation of Exclusive Right, approved by the Decree of the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183. Retrieved from: www.rada.gov.ua (in Ukrainian).

Constitution of Ukraine of 28 June 1996. Retrieved from: www.rada.gov.ua (in Ukrainian).

Consultative Group on International Agricultural Research. (1992). *Intellectual property issues for the international agricultural research centers*. Washington D.C.: Barton, J. & Siebeck, W.

Correa, C.M. (1995). Sovereign and property rights over plant genetic resources. *Agriculture and Human Values*. 12 (4), 58-79.

Correa, C.M. (1996). Access to genetic resources. *World Competition*, 20(3), 57 – 91.

Cottier, T. (1998). The protection of genetic resources and traditional knowledge: towards more specific rights and obligations in World Trade Law. *Journal of International Economic Law*, 1, 555-584.

Council of Europe (1953). European Convention on Human Rights from September 9, 1953. Retrieved from: http://www.echr.coe.int/Documents/Convention_ENG.pdf

Council of Europe. *Ukraine – Member State*. Web-page of the Council of Europe. Retrieved from: http://www.coe.int/no/web/portal/ukraine

Criminal Code of Ukraine of April 5, 2001. Retrieved from: www.rada.gov.ua (in Ukrainian).

Cromer, J.D. (2007). It's Hard to Find a Good Pair of Genes: So Why Make Them Free for the Taking? The *UMKC Law Review*, 76, 505-523.

Declaration of Independence of Ukraine of August 24, 1991. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the Cabinet of Ministers of Ukraine "Procedure of Implementation of Control for Payment of Remuneration to the Authors of the Technologies and/or their Components" of May 22, 2013 No.351. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the Cabinet of Ministers of Ukraine of June 4, 2008 No.520. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the Cabinet of Ministers of Ukraine "Provisions on the Representatives on the Intellectual Property Rights (Patent Attorneys)" of August 10, 1994 No.545. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the Cabinet of Ministers of Ukraine "Provisions on the Representatives on the Intellectual Property Rights to Plant Varieties" of August 19, 2002 No.1183. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the President of Ukraine of August 30, 2000 No.1033. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the President of Ukraine of August 30, 2002 No.791. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the President of Ukraine of December 9, 2010 No. 1085/2010. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the President "On approval of the State Intellectual Property Service of Ukraine's Statute" of April 8, 2011 No. 436/2011. Retrieved from: www.rada.gov.ua (in Ukrainian).

Decree of the President of Ukraine "On Ratification of Regulations on State Intellectual Property Service of Ukraine" of April 8, 2011 No. 436/2011. Retrieved from: www.rada.gov.ua (in Ukrainian).

Dennis, M. (1999). Bioprospecting agreements: forging a comprehensive strategy for managing genetic resources on public lands. *Environs Environmental Law and Policy Journal*, 22 (2), 3-70.

Development Strategy of the Agricultural Sector Until 2020, approved by the Ordinance of the Cabinet of Ministers of Ukraine of October 17, 2013, No.806-p.

Dreyfuss, R.C. (2007). Creative lawmaking: A comment on Lionel Bently, copyright, translations, and relations between Britain and India in the nineteenth and early twentieth centuries. *Chicago-Kent Law Review,* 82(3), 1243 – 1250.

Economic Code of Ukraine, established by Law of Ukraine of January 16, 2003 No. 436-IV (effective as of January 1, 2004). Retrieved from: www.rada.gov.ua (in Ukrainian).

Edict of the President of Ukraine of November 26, 2001 No. 146/2001. Retrieved from: www.rada.gov.ua (in Ukrainian).

European Commission. (2012). *Options for an EU instrument for patent valorisation.* Brussels, the EU: The expert group on IPR valorization (rapporteur Meniere, Y.). Retrieved from: http://ec.europa.eu/enterprise/policies/innovation/files/options-eu-instrument-patent-valorisation_en.pdf

European Parliament (2012). Report "On development aspects of intellectual property rights on genetic resources: the impact on poverty reduction in developing countries" of 14 December 2012 No. 2012/2135 (INI). Retrieved from: http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2012-0423&language=EN

European Parliament (2013). Resolution "On development aspects of intellectual property rights on genetic resources: the impact on poverty reduction in developing countries" of 15 January 2013. Retrieved from: http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2013-0007+0+DOC+XML+V0//EN

Farmer's Rights: resource pages for decision-makers and practitioners. Retrieved from: http://www.farmersrights.org/

FAO. (1991). *Report of the Conference of FAO twenty-sixth session.* Rome, 9-27 November, 1991. Rome, Italy: Commission on Genetic Resources for Food and Agriculture. Retrieved from: http://www.fao.org/docrep/x5587E/x5587e00.htm

FAO. (1991). *Conference Resolution 3/91, adopted as Annex 3 to the International Undertaking on Plant Genetic Resources*. In Report of the Conference of FAO Twenty-sixth Session. Rome, 9-27 November, 1991. Rome, Italy: Commission on Genetic Resources for Food and Agriculture. Retrieved from: http://www.fao.org/docrep/x5587E/x5587e00.htm

FAO. (1983). *International Undertaking on Plant Genetic Resources for Food and Agriculture*. Rome, Italy: Commission on Genetic Resources for Food and Agriculture. Retrieved from: http://www.fao.org/Ag/cgrfa/iu.htm

FAO. (2001). *Economic impacts of genetically modified foods on the agriculture sector: A synthesis.* Directorate-General for Agriculture: Bonguyi, M., Billingsley, G. & Emeka Nwagwu, W.Y.

FAO Commission on Genetic Resources. (2002). *Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agrobiodiversity and Agricultural Production Systems*. Background Study Paper No. 15. Rome, Italy: Visser, B., Eaton, D., Louwaars, N., Meer, I.V.D., Beekwilder, J. & Tongeren, F. (2002). Retrieved from: http://www.planttreaty.org/content/potential-impacts-genetic-use-restriction-technologies-gurts-agrobiodiversity-and-agricultur

Frison, C. (2006). The principles of sustainable development in the context of the international treaty on plant genetic resources in food and agriculture. *McGill International Journal of Sustainable Development Law and Policy*, 2(2), 155-174.

General amount of income by the regions of Ukraine (in Ukrainian) [Data file]. In *Taxes and Accounting* online. Retrieved from: http://www.nibu.factor.ua/ukr/info/socposobiya/sred-zarp-reg/

Giampietro M. (2002). The precautionary principle and ecological hazards of genetically modified organisms. *Ambio*, 31(6), 466-70.

Hubicki, S. & Sherman, B. (2005). Terminator genes as "technical" protection measures for patents? In Ch.Heath & A.K. Sanders (eds.), *New Frontiers of Intellectual Property Law: IP and Cultural Heritage, Geographical Indications, Enforcement and Overprotection* (pp.267-291). Studies in Industrial Property and Copyright Law, 25. Oxford, UK: Hart Publishing.

Hubicki, S. & Sherman, B. (2005). The killing fields: intellectual property and genetic use restriction technologies (2005). *University of New South Wales Law Journal*, 28 (3), 740-757.

Hunt, A. & Wickham, G. (1998). *Foucault and law: Towards a sociology of law as governance*. London: Pluto Press.

Institute of Food Biotechnology and Genomics of the National Academy of Sciences of Ukraine [Data file]. Retrieved from: http://ifbg.org.ua/

Instructions for Conducting Examination of Livestock Breeding by DNA-markers, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine on June 6, 2004. Retrieved from: www.rada.gov.ua (in Ukrainian).

Instructions of Execution of Cytogenetic Control for Livestock Breeding, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine on June 1, 2004. Retrieved from: www.rada.gov.ua (in Ukrainian).

International Convention for the Protection of New Varieties of Plants of December 2, 1961, as revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991.

Jeffery, M.I. (2002). Bioprospecting: Access to genetic resources and benefit-sharing under the Convention on Biodiversity and the Bonn Guidelines. *Singapore Journal of International and Comparative Law*, 6, 747-808.

Jørem, A. & Tvedt, M.W. (2014). Bioprospecting in the High Seas: existing rights and obligations in view of a new legal regime for marine areas beyond national jurisdiction. *International Journal of Marine and Coastal Law*, 29(2), 321-343.

Kapoor, M. (2012). Proposal for resolution to challenges posed by DNA sequence patents on the development of multiplex genetic tests. *Houston Law Review*, 49, 131-160.

Kate, K. & Laird, S.A. (1999). T*he commercial use of biodiversity: Access to genetic resources and benefit-sharing*. London: Earthscan Publications Ltd.

Kennedy, R. (2006). International conflicts over plant genetic resources: future developments? *Tulane Environmental Law Journal*, 20(1), 1-42.

Kiss, A. & Shelton, D. (2007). *Guide to International Environmental Law*. Leiden\Boston: Martinus Nijhoff Publishers.

Kloppenburg, J.R. (1988). *First the Seed: The Political Economy of Plant Biotechnology*. Cambridge, UK: Cambridge University Press.

Kloppenburg, J. (2008). *Seeds, sovereignty, and the vía campesina: plants, property, and the promise of open source biology*. Proceedings, *Workshop on Food Sovereignty: Theory, Praxis and Power.* St. Andrews College, University of Saskatchewan, Saskatoon, Saskatchewan, Canada: November, 17-18, 2008. Retrieved from: http://www.fao.org/publications/sofi/en/

Kovacic, W. E. & Reindl, A. P. (2004). An interdisciplinary approach to improving competition policy and intellectual property policy. *Fordham International Law Journal*, 28, 1062 – 1090.

Labour Code of Ukraine of December 10, 1971. Retrieved from: www.rada.gov.ua (in Ukrainian).

Laliberté, Br., Engels, J., & Fowler, C. (2000). The International Undertaking on Plant Genetic Resources: Its relevance to botanic gardens. *Online archive of BGC News*, 3(5). Retrieved from: http://www.bgci.org/resources/article/0156/

Law of Ukraine “On Animal Breeding” of December 15, 1993 No. 3691-XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On Environmental Protection” of June 25, 1991 No.1264- XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Innovative Activity” of July 4, 2002, No.40-IV. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Insurance” of March 7, 1996 No. 85/96-BP. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On International Treaties” of June 29, 2004 No. 1906-15. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Legal Succession of Ukraine” of September 12, 1991 No. 1543-XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Pedigree Work in Livestock Breeding” of December 15, 1993 No.3691-XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Priority Directions of Development of Science and Engineering” of July 11, 2011. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Priority Orientations of Innovative Activity in Ukraine” of September 8, 2011 No. 3715-VI. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Protection of Rights to Plant Varieties” of April, 21, 1993 No. 3116-XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine “On Private International Law” of June 23, 2005 No. 2709-IV. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On Seeds and Planting Materials" of December 26, 2002 No. 411-IV. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On Science and Technical Activity" of December 13, 1991 No. 1977-XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On State Biosafety System for Developing, Testing, Transportation and Use Genetically Modified Organisms" of May 31, 2007 No.1103-V. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On the National Programme of Adaptation of Ukrainian Legislation in Compliance with the European Union" of March 18, 2004 No.1629-15. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law "On the State Biosafety System for Developing, Testing, Transportation and Use of Genetically Modified Organisms" of May 31, 2007 No.1103-V. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On State Regulation of the Activity in the Field of Technology Transfer" of September 14, 2006 No.143-V. Retrieved from: www.rada.gov.ua (in Ukrainian).

Law of Ukraine "On the State Secret" of January 21, 1994 No.3855-XII. Retrieved from: www.rada.gov.ua (in Ukrainian).

Leary, D. (2012). Moving the marine genetic resources debate forward: some reflections. *The International Journal of Marine and Coastal Law*, 27, 435–448.

Leskien, D. & Flitner, M. (1997). Intellectual property rights and plant genetic resources: Options for a *Sui Generis System. Issues in Genetic Resources,* 6. Rome, Italy: International Plant Genetic Resources Institute.

Letter of the President of Ukraine to the Parliament of Ukraine "European Choice. Conceptual Foundations of Strategy of Economic and Social Development of Ukraine for 2002-2011 years" of April 30, 2002. Retrieved from: www.rada.gov.ua (in Ukrainian).

License Provisions for Pursuit of Economic Activity on Trade by Pedigree (Genetic) Resources, Execution of Genetic Examination for Origin and Abnormalities of Animals, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine on October 1, 2012 No.589. Retrieved from: www.rada.gov.ua (in Ukrainian).

Lightbourne, M. (2009). The FAO multilateral system for plant genetic resources for food and agriculture: better than bilateralism? *Journal of Law and Policy*, 30, 465-507.

Linarelli, J. (2004). Treaty governance, intellectual property and biodiversity. *Environmental Law Review*, 6, 21-38.

List of the Varieties of Plants the Rights to Which Belong to the Patentee Over the Period 2006, approved by the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183. Retrieved from: www.rada.gov.ua (in Ukrainian).

Locke, J. (1689). *The two treatises of civil government* (Hollis ed.). Retrieved from: http://oll.libertyfund.org/titles/222

Long, J. (2013). Global food security and intellectual property rights. *Michigan State International Law Review*, 21, 115-123.

Lushpaev, S.O. (2011). Some aspects of the concept of food security of Ukraine. *Chasopys Kievskogo Universiteta Prava*, 2, 211-214 (in Ukrainian).

Lutsenko, I. (2013). Royalty for Rejectionists. *Agobusiness Today*, 5(525) (in Ukrainian). Retrieved from: http://www.agro-business.com.ua/u-pravovomu-poli/1494-roialti-dlia-selektsioneriv.html

Maguire, J. Wai-Shing (2012). The seed 2.0: evolving intellectual property rights of agricultural germplasm. *Buffalo Intellectual Property Law Journal*, 8, 51-71.

Maloney, T. (2005). The enforcement of patent rights in the United States. In Ch.Heath & A.K. Sanders (eds.), *Patent enforcement worldwide. A survey of 15 countries. Writing in*

honour of Dieter Stauder (pp. 381-420). 2nd ed. Studies in Industrial Property and Copyright Law, 23. Oxford, UK, Portland, Oregon, the USA: Hart Publishing.

Malysh, N. *(2013)*. Genetically modified organisms in the system of food security of Ukraine. *Public Administration: Theory and Practice*, 2(14), 116-122 (in Ukrainian).

Marden, E. & Godfrey, R.N. (2012). Intellectual property and sharing regimes in agricultural genomics: finding the right balance for innovation. *Drake Journal ofAgricultural Law*, 17 (2), 369-393.

Matthews, D. (2007). The role of international NGOs in the intellectual property policy-making and norm-setting activities of multilateral institutions. *Chicago-Kent Law Review*, 82, 1369-1387.

McManis, Ch. (2008). Teaching current trends and future developments in intellectual property. *Saint Louis University Law Journal*, 52, 855-875.

Ministry for Environmental Protection of Ukraine. (2007). *National Environmental Policy of Ukraine: assessment and development strategy*. Kiyv, Ukraine: Ministry for Environmental Protection of Ukraine, Global Environmental Facility, United Nations Development Programme. Retrieved from: www.undp.org.ua/files/en_26469national-main.pdf

National Action Plan for 2013 in Respect of the Implementation of Economic Reforms for 2010-2014 years "On Rich Society, Competitive Economy, Effective State". Decree of the President of Ukraine of March 3, 2013 No.128/2013. Retrieved from: www.rada.gov.ua (in Ukrainian)

National Programme for Establishment of the National Ecological Network in Ukraine for 2000-2015, approved by Law of Ukraine of September 21, 2000. Retrieved from: www.rada.gov.ua (in Ukrainian).

National Standard No.4 "Appraisal of Intellectual Property Rights", approved by the Order of the Cabinet of Ministers of Ukraine of October 3, 2007 No. 1185. Retrieved from: www.rada.gov.ua (in Ukrainian).

Odek, J.O. (1994). Bio-piracy: creating proprietary rights in plant genetic resources. *Journal of Intellectual Property Law*, 2, 141-181.

Oguamanam, C. (2009). Canada: time to take access and benefit sharing over genetic resources seriously. *University of New Brunswick Law School Journal*, 60, 139-149.

Order of the Cabinet of Ministers of Ukraine of October 12, 1994 No.705. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of Ministry of Agrarian Policy and Food of Ukraine of July 17, 2001 No. 215/66. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of the Ministry of Agrarian Policy of Ukraine of July 21, 2003 No.244. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of the Ministry of Agrarian Policy of Ukraine "Resolution on the Certificate of the Authorship to Plant Varieties" of May 28, 2003 No.151. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of the Cabinet of Ministers of Ukraine of December 23, 2004 No.1716. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of the Ministry of Agrarian Policy in Ukraine "Rules of Filling and Filing of the Application to Plant Varieties" of April 26, 2007 No.287. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of the Ministry of Agrarian Policy and Food of Ukraine "Regulations on the State Register of the Subjects of Pedigree in Livestock Breeding" of June 13, 2012 No.358. Retrieved from: www.rada.gov.ua (in Ukrainian).

Ordinance of the Cabinet of Ministers of Ukraine "On designation of the Scientific Institute, Authorized on Performing Functions of Scientific-Methodological Centre on Issue of the

GMO's Examinations" of October 10, 2012 No. 761-p. Retrieved from: www.rada.gov.ua (in Ukrainian).

Order of the Ministry of Agrarian Policy and Food of Ukraine "List of Issues Subject to Execution of the State Supervision of Compliance With the State Legal Requirements by Market Participants by the State Inspection of Agriculture of Ukraine and its Local Authorities" of August 16, 2013 No.503. Retrieved from: www.rada.gov.ua (in Ukrainian).

Petrov, R. (2003). How far to endeavour? Recent developments in the adaptation of Ukrainian legislation to EU laws. *European Foreign Affairs Review*, 8 (1), 125-141. Retrieved from: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1374605

Powers, M.A. (1993). The United Nations Framework Convention on Biological Diversity: will biodiversity preservation be enhanced through its provisions concerning biotechnology intellectual property rights? *Wisconsin International Law Journal*, 12(1), 103-124.

Procedure of the Estimation of the Assessed Value of the Intellectual Property Rights Which Belong to the State Property or Were Created (Acquired) for Public Funds to Enroll in the Accounting, approved by the Order of the State Property Fund of Ukraine of December 13, 2005 No.3162. Retrieved from: www.rada.gov.ua (in Ukrainian).

Procedure of the Examination of the Storage Ability of Plant Varieties, approved by the Order of the Ministry of Agrarian Policy of Ukraine of July 21, 2003 No.246. Retrieved from: www.rada.gov.ua (in Ukrainian).

Programme of Integration of Ukraine into the European Union, approved by the President's Decree of September 14, 2000 No.1072/2000. Retrieved from: www.rada.gov.ua (in Ukrainian).

Protocol of Accession of Ukraine to the WTO of April 10, 2008. Retrieved from: www.rada.gov.ua (in Ukrainian).

Provisions on the State Inspection of Agriculture of Ukraine, approved by the President's Order of April 13, 2011 No. 459/2011. Retrieved from: www.rada.gov.ua (in Ukrainian).

Provisions on the State Veterinarian and Phytosanitary Service of Ukraine, approved by the Order of the President of Ukraine of April 13, 2011 No.464/2011. Retrieved from: www.rada.gov.ua (in Ukrainian).

Regulation of the Cabinet of Ministers of Ukraine of July 7, 2013 No.700. Retrieved from: www.rada.gov.ua (in Ukrainian).

Report on the work of the United Nations open-ended informal consultative process on oceans and the Law of the Sea at its eighth meeting (2007). New York, the USA: *Ocean Yearbook*, 22, 725 – 757.

Resolution of the Plenary Session of the Superior Economic Court of Ukraine of October 17, 2012. Retrieved from: www.rada.gov.ua (in Ukrainian).

Resolution on the Representatives Regarding Intellectual Property Rights (Patent Agents), approved by the Decree of the Cabinet of Ministers of Ukraine of August 10, 1994 No.545. Retrieved from: www.rada.gov.ua (in Ukrainian).

Sadova, I. (2014). European line: Numbers and facts. *Agrobusiness Today*, 15-16, 286-287. Retrieved from: http://www.agro-business.com.ua/2012-07-07-14-39-23/2326-2014-08-19-11-29-53.html (in Ukrainian).

Safrin, S. (2004). Hyperownership in a time of biothechnological promise: the international conflict to control the building blocks of life. *The American Journal Of International Law*, 98, 641-685.

Safrin, S. (2007). Chain reaction: how property begets property. *Notre Dame Law Review,* 82, 1917 – 1969.

Safrin, S. (2010). Providing public goods under International Law: of openness and enclosure. *American Society of International Law Proceedings,* 104**,** 148-153**.**

Salako, S.E. (2012). Agrobiotechnology, indigenous peoples' rights and traditional knowledge. *African Journal of International and Comparative Law*, 20(2), 318-332.

Semchik V.I. (2010). Legal regulation of ecological and innovative relationships in agriculture of Ukraine. In *International Environmental Law: State and Prospects* (pp.193-200). Kyiv, Ukraine: LLC "Publishing geographical literature" Horizons" (in Ukrainian).

Secretariat of the Convention on Biological Diversity. (2010). Fact sheets in the ABS series, Convention on biological diversity: ABS, Uses of genetic resources. Retrieved from: http://www.cbd.int/abs/infokit/factsheet-uses-en.pdf

Shemshuchenko, Y.S. (2005). *Selected: Theoretical problems of harmonization of Ukraine with the European law*. Kyiv, Ukraine: Publishing house "Yuridichna dumka" (in Ukrainian).

Shui, R.W. (2001). Discourse analysis in the legal context. In D. Tannen, D. Schiffrin, & H. Hamilton (eds.), *The Handbook of discourse analysis* (pp. 437-452). Oxford, UK: Blackwell Publishers.

Srinivas, K. R. (2008). Traditional knowledge and intellectual property rights: A note on issues, some solutions and some suggestions. *Asian Journal of WTO and International Health Law and Policy, 3(1), 81-120.*

State Program on Development of Ukrainian Village to 2015 on ORGANIC, approved by the Order of the Cabinet of Ministers of Septemder 19, 2007 No.1158. Retrieved from: www.rada.gov.ua (in Ukrainian).

Strategy of Integration of Ukraine, approved by the Presidential Decree of Ukraine "On Confirmation of Strategy of Integration of Ukraine into European Union" of June 11, 1998 No.615/98. Retrieved from: www.rada.gov.ua (in Ukrainian).

Subramanian, A. (1992). Genetic resources, biodiversity and environmental protection: an analysis, and proposals towards a solution. *Journal of World Trade*, 26, 105-109.

Tang, S. (2011). *A general theory of institutional change*. London, UK: Routledge.

Teisberg, E.O. (1991). *Why do good managers choose poor strategies*. Harvard Business School Case 9-391-172, 1-10.

The European Council Common Strategy 1999/CFSP of on Ukraine. Annex V to the Presidency Conclusions of December 10-11, 1999, Helsinki. Retrieved from: http://www.europarl.europa.eu/summits/hel2_en.htm#V

The Supreme Court of Ukraine Generalization of the legislation of January 1, 2006. Retrieved from: www.rada.gov.ua (in Ukrainian).

The World Bank. *Country and Lending Groups* [Data file]. Retrieved 10 February, 2015 from: http://data.worldbank.org/about/country-and-lending-groups

The World Bank. *Data on Ukraine* [Data file]. Retrieved 10 February, 2015 from: http://data.worldbank.org/country/ukraine

Thomas, D.J. & Dhar, P. (2008). Of squares pegs and round holes: Towards a new paradigm of database protection. *The Indian Journal of Law and Technology*, 4, 34-63.

Trading Economics. *Ukraine GDP per capita* [Data file]. Retrieved 1 December, 2014 from: http://www.tradingeconomics.com/ukraine/gdp-per-capita

Transparency International. *Corruption by country/territory: Ukraine* [Data file]. Retrieved 10 February, 2015 from: http://www.transparency.org/country#UKR

Tvedt, M.W. (2005). How will a substantive patent law treaty affect the public domain for genetic resources and biological material? *The Journal of World Intellectual Property*, 8(3), 311-344.

Tvedt, M.W. (2005). Intellectual property – rights or privileges? *The Journal of World Intellectual Property*", 8(3), 445-457.

Tvedt, M.W. (2007). The path to one universal patent. *Environmental Policy and Law*, 37 (4), 297-305.

Tvedt, M.W. & Finckenhagen, M. (2008). Scope of process patents in farm animal breeding. *Journal of World Intellectual Property*, 11(3), 203-228.

Tvedt, M.W. (2010). One Worldwide Patent System: what's in it for developing countries? *Third World Quarterly*, 31(2), 277-293.

Tvedt, M.W. & Ole K.(2011). Implementing the Nagoya Protocol on ABS: A hypothetical case study on enforcing benefit sharing in Norway by Fauchald Fridtjof Nansen Institute (FNI), Oslo, Norway, *The Journal of World Intellectual Property*, 14 (5), 383–402.

UN. (1992). *Convention on Biological Diversity* of June 5, 1992. Rio de Janeiro, Brazil: Earth Summit. Retrieved from: http://www.cbd.int/doc/legal/cbd-en.pdf

UN. (2000). *Cartagena Protocol on Biosafety to the Convention on Biological Diversity* of May 15, 2000. Montreal, Canada: Secretariat of the Convention on Biological Diversity. Retrieved from: http://bch.cbd.int/protocol/text/

UNDP. (2013). *Human Development Report* [Data file]. Retrieved on 1 December, 2014 from: http://www.undp.org/content/undp/en/home/librarypage/hdr/human-development-report-2013/

UNDP. (2013). *Ukraine: HDI value and rank changes in the 2013 Human Development Report*. Retrieved from: http://hdr.undp.org/sites/default/files/Country-Profiles/UKR.pdf

UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters from (Aarhus Convention; June 25, 1998; effective from October 30, 2001). Ratified by Law of Ukraine No. 832-XIV of July 6, 1999. Retrieved from: www.rada.gov.ua (in Ukrainian).

UNEP. (1972). *Declaration of the United Nations Conference on the Human Environment* of June 16, 1972. Retrieved from: http://www.unep.org

UNEP. (1995). Pan-European Biological and Landscape Diversity Strategy. Approved at the Ministerial Conference "Environment for Europe" (Sofia, Bulgaria, 23-25 October 1995). *Nature and Environment*, 74. Strasbourg, France: Council of Europe Press. Retrieved from: http://www.salzburg.gv.at/paneurop_strategie.pdf

UNESCO. (2005). *Universal Declaration on Bioethics and Human Rights* of October 19, 2005. Retrieved from: http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/bioethics-and-human-rights/

Van Dijk, T. (2001) Critical discourse analysis. In D.Schiffrin, D. Tannen and H. Hamilton (ed.), *The Handbook of discourse analysis* (pp. 352 – 371). Oxford, UK: Blackwell Publishers.

Vatn, A. (2005). *Institutions and the environment*. Cheltenham UK: Edward Elgar.

Vatn, A. (2009). *Institutions and the environment*. Massachussetts, the USA: Centre of Ecological Pollution Prevention (CEPP).

Venbrux, G. K. (2006). When two worlds collide: ownership of genetic resources under the Convention on Biological Diversity and the Agreement on Trade-Related Aspects of Intellectual Property Rights. *Pittsburgh Journal of Technology Law and Policy*, VI, 1-35.

Verkhovets, F. (2013). The philosophy of global survival: Traditions or GMOs. *Agrobusiness Today*, 20 (267). Retrieved from: http://www.agro-business.com.ua/dumky-pro-vazhlyve/1870-filosofiia-globalnogo-vyzhyvannia-tradytsiii-abo-gmo.html (in Ukrainian)

Walliman, N. (2006). *Social research methods*. London, UK: Sage Publications Ltd.

West, S. (2012). Institutionalised exclusion: The political economy of benefit sharing and intellectual property. *Law, Environment and Development Journal*, 8, 19-42.

Whitman, D.B. (2000) Genetically modified foods: Harmful or helpful? *Cambridge Scientific Abstract*, 1-13. Retrieved from: http://biomed.brown.edu/arise/resources/docs/GM%20foods%20review.pdf

WTO. (1994). *Agreement on Trade-Related Aspects of Intellectual Property Rights,* Annex 1C of the Marrakesh Agreement of 15 April 1994. Retrieved from: http://www.wto.org/english/docs_e/legal_e/27-trips.pdf

WTO. (1994). *Agreement on the Application of Sanitary and Phytosanitary Measures* of 15 April 1994. Retrieved from: *http://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm*

WTO. (1994). *Marrakesh Agreement Establishing the World Trade Organization* of 15 April 1994. Retrieved from: http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm

WTO. (2001). *Ministerial declaration* of 14 November 2001, Doha, Qatar. Retrieved from: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm

WTO. (2001). *Doha Declaration on the TRIPS agreement and public health* of 14 November 2001. Retrieved from: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

WTO. (2013). Experts say business models for pharmaceuticals must adapt to new circumstances. WHO-WIPO-WTO Symposium. 5 July 2013. *WTO: 2013 News Items*. Retrieved from: http://www.wto.org/english/news_e/news13_e/trip_05jul13_e.htm

Zedan, H. (2005). Patents and biopiracy: The search for appropriate policy and legal responses. *Brown Journal of World Affairs,* XII (1), 189-205.

Zewers, K.E. (2008). Bright future for marine genetic resources, bleak future for settlement of ownership rights: reflections on the United Nations Law of the Sea consultative process on marine genetic resources. *Loyola University Chicago International Law Review*, 5(2), 151-176.

APPENDICES

Appendix 1

Individual interview with an employee of the research institute

Answers, given by *Nikolai Kichigin* (Candidate of Legal Sciences, Leading research fellow of the Institute of Legislation and Comparative Law Under the Government of the Russian Federation) to the following questions.

1. Could you describe the process of signature of CBD and TRIPS by the Russian Federation?

CBD was ratified in 1995 on the ground of the Federal Law "On Ratification of Biological Diversity" No.16-FL of February 17, 1995. TRIPS was signed in 1994 at the Uruguayan round of GATT negotiations when the World Trade Organization was established. The Agreement came into force on August 22, 2012.

1. What were the main debates in the process of their ratification revolving around (from the environmental perspective)?

Among the issues discussed were the ability of the Russian Federation to execute the international obligations in accordance with CBD and TRIPS and the conformance of the requirements of given international agreements to the national interests of the Russian Federation. The methods and terms of the implementation of the requirements of CBD and TRIPS into the Russian legislation were also negotiated along with the risks and negative effects which could arise as a result of signing the agreements.

2. How successful was the implementation of CBD's and TRIPS's provisions in the Russian legislation? Please, make an evaluation.

According to the experts on intellectual property protection, in general, the unified laws on intellectual property of Russia meet the requirements established by TRIPS. And the authors of the fourth part of the Civil Code of the Russian Federation guarantee this. However, according to Makovsky A. L., the Russian Federation still will have to give serious consideration to the way particular problems of International Private Law in the intellectual

property field were resolved in the fourth part of the Civil Code of the Russian Federation (approved in 2006).

CBD was integrated into federal legislation by acceptance of Federal Law "On the Animal World" No.52-FZ on 24 April, 1995. The recitals to the Law state that this Federal Law regulates the relationships in the field of the protection of the animal world usage and the area of its habitat to provide biological diversity, constant use of its components and establishment of conditions for stable existence of the animal world, preservation of genetic fond of wild animals and any other protection of the animal world as an integral element of the environment.

The Law introduces the following concepts:

- biological diversity of the animal world is the diversity of the animal world as a part of one species, among the species and in ecosystems;
- steady existence of the animal world is the existence of the objects of the animal world during the long indefinite period of time;
- constant usage of the objects of the animal world is the usage of the objects of the animal world which does not lead to exhaustion of the biological diversity of the animal world in the long-term and preserves the ability of the animal world to reproduction and steady existence;
- protection of the animal world is the activity aimed at preserving the biological diversity and procurement of steady existence of the animal world and providing the conditions for steady usage and reproduction of the objects of the animal world.

3. What is the legal status of GMP's in Russia?

Term 'genetically modified products' is not present in the laws of the Russian Federation. However, the Federal Law "On Government Control on Genetic Engineering" No.86-FZ of June 5, 1996 defines the concept of 'genetically modified organisms'. The term means an organism or a few organisms, any noncellular, unicellular or multicellular organism able to reproduce and transfer essential genetic material different from natural organisms received through applying the methods of genetic engineering and containing genetic material including genes and their fragments and combinations of genes.

According to Article 11 of the Law "On Government Control on Genetic Engineering" No.86-FZ, the products (services) received via use of methods of genetic engineering comply with obligatory requirements as for environmental protection, pharmacopoeia items, sanitary-epidemiological requirements and other demands of the legislation of the Russian Federation.

In respect of the genetically modified products which are due to mandatory certification and conformity declaration, the certificate of conformity is issued or the declaration of conformity is approved in accordance with the established legislation of the Russian Federation on technical regulations.

The Administrative Regulation on Execution by Federal Veterinary and Phytosanitary Surveillance (Rosselkhoznadzor) of the function of state to carry out registration of feeds received with the application of genetically modified organisms was approved by the order of the Ministry of Agriculture of the Russian Federation No.466 of October 6, 2009.

In order to get the state registration for genetically modified feed, an applicant files or submits the following registration documents to Rosselkhoznadzor:

1) application for the state registration of genetically modified feed;
2) files containing:
    a) information about the origin of GM feed;
    b) evaluation of potential risk of usage of GM feed (comparing to initial basic feed) and recommendations of the applicant on elimination of such risk;
    c) details on possible usage of GM feed and registration and use of the feed in question abroad;
    d) details about the technology of rising of the sort of genetically modified plant used for receiving of this GM feed;
    e) details on the technology of the production of GM feed;
    f) the draft GM feed application instruction;
3) a copy of the certificate about entering into the State Register of Selection Achievements of a variety of plant allowed to be used for receiving the feed if the mentioned variety is capable of reproduction and aimed at further growing of biomass or fodder grain.

4. Are genetic resources patentable in Russia? What is their legal status?

The Federal Law "On Government Control on Genetic Engineering" No.86-FZ of June 5, 1996 does not define the concept of genetic resources. The concept of 'genetic resources' is defined by the Federal Law "On the Animal World" of April 24, 1995 No.52-FZ. Genetic resources of the animal world are the part of biological resources including genetic material of the animal origin containing the functional units of hereditary background. The genetic resources are not directly defined as the objects of patent rights in the Civil Code of the Russian Federation (part 4). The term 'genetic resources' is not used in the Code. However, according to Article 1349 of the Civil Code of the Russian Federation the objects of patent rights are the results of intellectual activity in science and technology industry which meet the requirements for inventions and useful models established by the present Code and the results of intellectual property in regard to design which comply with the requirements for industrial units established by the Code.

The following objects are not patentable in the Russian Federation:

1) the ways of cloning people;
2) the ways of modification of genetic unity of cells of human germ line;
3) usage of human embryos for industrial and commercial goals;
4) other patent claims that may contradict social interests and principles of humanity and morality.

Thus, the Law does not include any direct prohibition of acknowledgement of genetic resources of the objects of patent rights with limited exceptions.

Article 1350 of the Civil Code of the Russian Federation defines the conditions of patentability of the invention. Technical decision is protected as an invention in any industry in respect of the product (particularly the device, substance, strain of microorganism, cultures of cells of plants or animals) or method (process of execution of the actions on material object by means of funds).

The legal protection is not provided to the sorts of the plants, breeds and biological methods of receiving them, excluding microbiological ways and products received via such methods.

The comments to the Civil Code of the Russian Federation state that the *substances* include – chemical compounding such as nucleon proteins and acids; compositions (mixture,

speciation); products of nuclear transformation. *Strains of organisms* include strains of bacteria, viruses, bacteriophages, microalgae, microfungus, consortiums of microorganisms. *The lines of the cells of plants* and animals include the lines of the cells of tissues, organs of plants or animals, consortiums of correspondent cells. The genetic constructions include plasmids, vectors, stable transformed cells of microorganisms of plants and animals, transgenic plans.

Appendix 2

Some international environmental treaties, signed by Ukraine

1. Agreement on cooperation in the conservation and use of genetic resources of cultivated plants of CIS countries (June 4, 1999); ratified by Law of Ukraine No. 1452-III of February 10, 2000.
2. Cartagena Protocol on Biosafety to the Convention on Biological Diversity (May 15, 2000; effective from September 11, 2003); ratified by Law of Ukraine No. 152-IV of September 12, 2002.
3. Convention on Biological Diversity (June 5, 1992; effective from December 29, 1993); ratified by Law of Ukraine No.257/94-VR of November 29, 1994.
4. Convention on the Conservation of Migratory Species of Wild Animals (Bonn Convention; June 23, 1979; effective from November 1, 1983); Ukraine acceded to the Convention on March 19,1999 by adopting Law No.535-XIV.
5. Convention on the Conservation of European Wildlife and Natural Habitats (Bern Convention; September 19, 1979; effective as of June 1, 1982); ratified by Law of Ukraine No.436/96-BP of October 29, 1996.
6. Convention on Environmental Impact Assessment in a Transboundary Context (the Espoo Convention; February 25, 1991); ratified by Law of Ukraine No. 534-XIV of July 20, 1999.
7. Declaration of the United Nations Conference on the Human Environment (Stockholm Declaration) (June 16, 1972).
8. FAO International Treaty on Plant Genetic Resources for Food and Agriculture (November 3, 2001).
9. Framework Convention on the Protection and Sustainable Development of the Carpathians (May 22, 2003); ratified by Law of Ukraine No. 1672-IV of April 7, 2004.
10. International Convention for the Protection of New Varieties of Plants of December 2, 1961, as revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991.
11. International Covenant on Civil and Political Rights (December 16, 1966; effective as of March 23, 1976).

12. International Covenant on Economic, Social and Cultural Rights (December 16, 1966; effective as of January 3, 1976).
13. Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety (October 15, 2010; it will enter into force on the ninetieth day after the date of deposit of the 40th instrument of ratification).
14. Kyoto Protocol to the United Nations Framework Convention on Climate Change (UNFCCC; December 11, 1997); ratified by Law of Ukraine No. 1430-IV of February 4, 2004.
15. Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation, and the strategy to mobilise resources for global biodiversity (October 29, 2010; it will enter into force on the ninetieth day after the date of deposit of the 50th instrument of ratification); (Ukraine acceded to it on January 31, 2012).
16. Pan-European Biological and Landscape Diversity Strategy (PEBLDS) (October 25, 1995).
17. Protocol on Strategic Environmental Assessment (Kyiv, May 21, 2003).
18. Rio Declaration on Environment and Development (June 4, 1992).
19. UNECE Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters from (Aarhus Convention; June 25, 1998; effective from October 30, 2001); ratified by Law of Ukraine No. 832-XIV of July 6, 1999.
20. United Nations Framework Convention on Climate Change (UNFCCC; May 9, 1992); ratified by Law Ukraine No. 435/96-BP of October 29, 1996.
21. Universal Declaration on Bioethics and Human Rights of October 19, 2005 (UNESCO).
22. Universal Declaration on Human Rights (December 10, 1948).
23. UN's Convention on Biological Diversity (CBD; June 5, 1992) (ratified by Law of Ukraine No.257/94-BP of November 29, 1994).

Appendix 3

Some international treaties on IPRs, signed by Ukraine

1. The framework of the *International Patent Cooperation Union.*

1) Patent Cooperation Treaty (Done at Washington on June 19, 1970, amended on September 28, 1979, modified on February 3, 1984, and on October 3, 2001(effective as of April 1, 2002).
2) Patent Law Treaty (June 1, 2000); ratified by Law of Ukraine No.245-IV of November 22, 2002).

2. The framework of *the WIPO.*

1) Agreement between the Cabinet of Ministers of Ukraine and the World Intellectual Property Organization (approved by the Decree of the Cabinet of Ministers of Ukraine's No.1421 of September 26, 2002).
2) Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (April 28, 1977, and amended on September 26, 1980).
3) Convention Establishing the World Intellectual Property Organization (Stockholm, July 14, 1967 and amended on September 28, 1979).
4) Paris Convention for the Protection of Industrial Property (March 20, 1883); effective for the USSR from July 1, 1965, and for Ukraine – from December 25, 1991.
5) Patent Cooperation Treaty (June 19, 1970); effective in Ukraine from December 25, 1991.
6) Strasbourg Agreement Concerning the International Patent Classification (March 24, 1971, amended on September 28, 1979).

3. The framework of the *WTO.*

Agreement on Trade-Related Aspects of Intellectual Property Rights in Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization (April 15, 1994).

4. The framework of *the Commonwealth of Independent States (CIS).*

1) Agreement on Cooperation in the Field of Legal Protection and the Defense of Intellectual Property and the Establishment of the Interstate Council on the Legal Protection and Defense the Intellectual Property (November 19, 2010); ratified by Law of Ukraine No.4211-VI of December 21, 2011.

2) Agreement on Mutual Provision of Safety of the Interstate Secrets in the Sphere of Legal Protection of Inventions (Minsk, June 4 1999).

5. *Multilateral agreements*

The International Convention for the Protection of New Varieties of Plants (December 2, 1961, revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991).

Appendix 4

List of Ukrainian legal acts regarding IPRs to GMPs

All Ukrainian legislation is available on the Web-site of the Parliament of Ukraine: www.rada.gov.ua

1. Civil Code of Ukraine, established by Law of Ukraine of January 16, 2003 No.435-I (effective as of January 1, 2004).
2. Code of Ukraine on Administrative Offenses, established by Law of Ukraine of December 7, 1984 No.8073-X.
3. Conditions of the Legal Interests of the Owner of Plant Varieties in Case of the Limitation of Exclusive Right, approved by the Decree of the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183.
4. Criminal Code of Ukraine, established by Law of Ukraine of April 05, 2001 No.2341-III (effective as of September 1, 2001).
5. Criteria of the Prohibition to Distribute Varieties in Ukraine, approved by the Order of the Ministry of Agrarian Policy of Ukraine of August 30, 2002 No.247.
6. DSTU 3574-97 Patent Card. Basic Provisions. Drawing up and Execution Procedure Effective as of 1998-01-01.
7. Economic Code of Ukraine, established by Law of Ukraine of January 16, 2003 No. 436-IV (effective as of January 1, 2004).
8. Guidelines for Procurement With Samples for Qualified Examination of Plant Varieties for Suitability for Distribution, approved by the Order of the Ministry of Agrarian Policy of Ukraine of December 15, 2009 No.896.
9. Instructions of Conducting of Immunogenotypic Researches of livestock breeding, approved by the Order of the Ministry of Agrarian Policy of Ukraine of June 6, 2004 No.197.
10. Instruction on the Order of Familiarization by Any Person With the Application Materials to the Object of Intellectual Property Rights, approved by the Order of Ministry of Education and Science of Ukraine of April 22, 2005 No. 247.
11. License Provisions for Pursuit of Economic Activity on Trade by Pedigree (Genetic) Resources, Execution of Genetic Examination for Origin and Abnormalities of Animals,

approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine of October 1, 2012 No.589.

12. List of Issues Subject to Execution of the State Supervision of Compliance With the State Legal Requirements by Market Participants by the State Inspection of Agriculture of Ukraine and its Local Authorities, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine of August 16, 2013 No.503.
13. List of Variaties and Sorts of the Plants the Rights to Which Belong to the Patentee Over the Period of 2006, approved by the Decree of the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183.
14. Mid-term priority lines of the invention activity at nationwide level for 2012-2016 years, approved by the Cabinet of Ministers of Ukraine on March 12, 2012 No.294.
15. National Action Plan for 2013 in respect of the Implementation of Economic Reforms for 2010-2014 years "On Rich Society, Competitive Economy, Effective State". Decree of the President of Ukraine of March 3, 2013 No.128/2013.
16. National Standard No.4 "Evaluation of Intellectual Property Rights", approved by the Cabinet of Ministers of Ukraine on October 3, 2007 No.1185.
17. Nationwide Complex Programme of the Development of High Science Absorbent Technologies, approved by the Law of Ukraine of April 9, 2004 No.1676-IV.
18. On Approval of Minimal Rate of Remuneration to the Authors of Technologies and Individuals Who Perform Their Transfer. Decree of the Cabinet of Ministers of Ukraine of June 4, 2008 No. 520.
19. On Certain Issues of Accommodation of Disputes Regarding the Protection of the Intellectual Property Rights. Resolution of the Plenary Session of the Higher Commercial Court of Ukraine of October 10,2012 No.12.
20. On designation of the Scientific Institute, Authorized on Performing Functions of Scientific-Methodological Centre on Issue of the GMO's Examinations. Ordinance of the Cabinet of Ministers of Ukraine of October 10, 2012 No. 761-p.
21. On Innovative Activity. Law of Ukraine of July 4, 2002 No.40-IV.
22. On Land Protection. Law of Ukraine of June 6, 2003 No.962-IV.
23. On Pedigree Work in Livestock Breeding. Law of Ukraine of December 15, 1993 No.3691-XII
24. On Priority Fields of Development of Science and Engineering. Law of Ukraine of July 11, 2011 No.2623.

25. On Priority Orientations of Innovative Activity in Ukraine. Law of Ukraine of September 8, 2011 No. 3715-VI.
26. On Protection of Rights to Inventions and Utility Models. Law of Ukraine of December 15, 1993 No.3687-XII.
27. On Protection of Rights to Plant Varieties. Law of Ukraine of April 21, 1993 No.3116-XII.
28. On Regulation of the State Register of Patents and Declarative Patents of Ukraine for Secret Inventions. Order of Ministry of Education and Science of Ukraine of November 14 2001 No.739.
29. On Some Issues of the Enforcement of the Law of Ukraine "On the State Regulation of the Activity in the Technology Transfer Field". Decree of the Cabinet of Ministers of Ukraine of August 1, 2007 No. 995.
30. On State Regulation of the Activity in the Field of Technology Transfer. Law of Ukraine of September 14, 2006 No.143-V.
31. On the Order of Payment of Remuneration to Authors of Inventions and Industrial Designs That Protected by the USSR Certificates in Effect in Ukraine". Resolution of Cabinet of Ministers of Ukraine of July 11, 1994 No. 473.
32. On the Ways of Enforcement of the Law of Ukraine "On the Protection of the Rights to Plant Verities". Decree of the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183.
33. Procedure of the Estimation of the Assessed Value of the Intellectual Property Rights, Which Belong to the State Property or Were Created (Acquired) for Public Funds to Enroll in the Accounting, approved by the Order of the State Property Fund of Ukraine of December 13, 2005 No.3162.
34. Procedure of the Approbation and Registration of the Selection Achievements, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine of July 2, 2012 No.385.
35. Procedure of the Examination of the Storage Ability of Plant Varieties, approved by the Order of the Ministry of Agrarian Policy of Ukraine of July 21, 2003 No.246.
36. Programme of Integration of Ukraine into the European Union, approved by the President's Decree of September 14, 2000 No.1072/2000.
37. Procedure of Implementation of Control for Payment of Renumeration to the Authors of the Technologies and/or their Components, approved by the Decree of the Cabinet of Ministers of Ukraine of May 22, 2013 No.351.

38. Procedure of Payment of Fees in Relation to Protection of the Rights to the Plant Varieties, approved by the Decree of the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183.
39. Procedure for Payment of Fees for the Activities Related to the Protection of Rights to the Object of Intellectual Property, approved by the Order of the Cabinet of Ministers of Ukraine of December 23, 2004, No.1716.
40. Provisions on the Representatives on the Intellectual Property Rights to Plant Varieties, approved by the Decree of the Cabinet of Ministers of Ukraine of August 19, 2002 No.1183.
41. Provisions on the State Inspection of Agriculture of Ukraine, approved by the President's Order of April 13, 2011 No. 459/2011.
42. Provisions on the State Veterinarian and Phytosanitary Service of Ukraine, approved by the Order of the President of Ukraine of April 13, 2011 No.464/2011.
43. Recommendations of Parliamentary Hearings on the Following Subject: "National Innovative System of Ukraine: Problems of Formation and Realization", approved by the Decree of The Parliament of Ukraine of July 27, 2007.
44. Regulations on Certification of Pedigree (Genetic) Resources, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine of November 17, 2011 No. 629.
45. Regulations on the Ministry of Agrarian Policy and Food of Ukraine, approved by the Order of the President of Ukraine of April 23, 2011 No. 500/2011.
46. Regulations on the Tender Committee for Choosing of the Recipients of the Budget Funds for Introduction of the Selection Programme in the Livestock and Bird Breeding at the Enterprises of Agro-Industry, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine of August 10, No.499.
47. Regulations on the State Register of the Subjects of Pedigree in Livestock Breeding, approved by the Order of the Ministry of Agrarian Policy and Food of Ukraine of June 13, 2012 No.358.
48. Resolution on the Certificate of the Authorship to Plant Varieties, approved by the Order of the Ministry of Agrarian Policy of Ukraine of May 28, 2003 No.151.
49. Regulations of Conferment of Appropriate Status to the Subjects of Pedigree work at Livestock Breeding, approved by the Order of the Ministry of Agrarian Policy and Food and Ukrainian Academy of Agrarian Sciences of July 17, 2001 No.215/66.

50. Resolution on the Representatives Regarding the Intellectual Property Rights (Patent Agents), approved by the Decree of the Cabinet of Ministers of Ukraine of August 10, 1994 No.545.
51. Resolution on the State Register of the Intellectual Property Rights to Plant Varieties and Granting of Patents to Plant Varieties in Ukraine, approved by the Order of the Ministry of Agrarian Policy of Ukraine of December 13, 2002 No.390.
52. Resolution on the State Register of the Applications for Plant Varieties, approved by the Order of the Ministry of Agrarian Policy of Ukraine of February 26, 2003 No.42.
53. Resolution on the State Register of the Plant Varieties Suitable for Distribution in Ukraine, approved by the Decree of the Cabinet of Ministers of Ukraine of May 15, 2003 No.686.
54. Rules of Filling and Filing of the Application to Plant Varieties, approved by the Order of the Ministry of Agrarian Policy in Ukraine of April 26, 2007 No.287.

Appendix 5

Comparison of CBD and TRIPS

	TRIPS	*CBD*
Type of rights	Private property rights	Sovereign rights
Genetic resources as	Private property	Common heritage, common pool resources. As variant, traditional resources rights
Protected actors	Legal entities and researchers from:	
	developed countries	developing countries; indigenous people
Differences in geographical location of actors	mostly North	mostly South
Role of actors - who controls the flow of plant genetic resources	Producers	countries of genetics' origin, and consumers
Values, preferences	Economic welfare, money, income	Environmental and social welfare (nature, health, livelihood, religion, traditions)
Access to genetic resources	Limited Access (limited by patent)	Open access
Type of social relations	Ownership, private relationship; competition of multinational companies and their distribution power over GMP.	Public relationship
Establishment of market	Use of patent, according to TRIPs	According to the national legislation, and by making agreement on specific subject (CBD agreement or Material Transfer Agreements (MTAs)

Table 1. General comparison of TRIPS and CBD. Table, where some notions to the Table "TRIPS (WTO) vs CBD", that was presented by Arild Vatn in the lecture "International Environmental Agreements" from 23 October 2012 (to the course EDS 304 at the NMBU) have been added.

Appendix 6

Some legislative acts of Ukraine regarding its integration into the EU

1. Agreement for Partnership and Cooperation between the European Communities and their Member States, and Ukraine (June 14, 1994; came into force on March 1, 1998), ratified by Law of Ukraine No.237/94-VR of November 10, 1994.
2. Action Plan "Ukraine-EU", approved by the Ordinance of the Cabinet of Ministers of Ukraine of February 12, 2005 No.36-r.
3. European Choice. Conceptual Foundations of the Strategy of Economic and Social Development of Ukraine for 2002-2011 years. Letter of the President of Ukraine to The Parliament of Ukraine of April 30, 2002.
4. Issues on Organizing the Execution of the Law of Ukraine "On the National Program of Adapting Ukraine's Legislation to E.U. Legislation". Decree of the President of Ukraine of August, 21, 2004 No.965/2004.
5. On Approval of Plan of Measures for Executing in 2005 of a National Program of Adapting Ukraine's Legislation to European Union Legislation. Resolution of the Cabinet of Ministers of Ukraine of June 16, 2005 No.201-p.
6. On Approval of the State Target Program of Development of the Ukrainian Village until 2015. Resolution of the Cabinet of Ministers of Ukraine of September 19, 2007 No.1158.
7. On Approval of the Order of Translation of the 'Acquis Communautaire' Acts Into Ukrainian. Order of the Ministry of Justice of Ukraine of June 08, 2005 No.56/5.
8. On Conception on Adaptation of Ukrainian Legislation to the Legislation of European Union. Decree of the Cabinet of Ministers of Ukraine of August 16, 1999 No.1496.
9. On Confirmation of the Strategy of Integration of Ukraine into European Union. Decree of the President of Ukraine of June 11, 1998 No.615/98.
10. On ensuring the execution of the agreement on partnership and cooperation between Ukraine and the European Communities (the European Union) and improving the mechanism of cooperation with the European Communities (the European Union). Decree of the President of Ukraine of February 24, 1998 No.148.
11. On Ordering the Process of Examining Laws of Ukraine and Other Legislative Acts for Their Conformity to "Acquis Communautaire". Order of the Ministry of Justice of Ukraine of April 28, 2005 No.42/5.

12. On the Concept of a State Programme for Adaptation of Ukrainian Legislation to the EU Legislation. Law of Ukraine of November, 21, 2002 No.228-IV.
13. On the Fundamental Principles of the State Agricultural Policy for the Period till 2015. Law of Ukraine of October 18, 2005 No.2982-IV.
14. On the National Programme of Adaptation of Ukrainian Legislation in Compliance with the European Union. Law of Ukraine of March 18, 2004 No.1629-IV.
15. Plan of Primary Action on Executing an Agreement on Partnership and Cooperation Between Ukraine and the EU, and Improving Institutional Support for the Activity of Executive Authorities in the Field of European Integration, approved by Resolution of the Cabinet of Ministers of June 28, 2003 No.382-p.
16. Programme of Ukraine's Integration into the European Union, approved by Decree of the President of Ukraine of September 14, 2000 No.1072/2000.
17. Recommendations After Parliamentary Hearings in Issues of Realization of the Governmental Policy on Integration of Ukraine to the EU. Decree of the The Parliament of Ukraine of January 17, 2002 No.2999-III.
18. Strategic Plan for Transformation of System of Technical Regulation and Consumer Right's Protection under the World Trade Organization and the European Union Requirements for the period 2007-2010, approved by the Order of the State Committee for Technical Regulation and Consumer Policy of Ukraine on August 9, 2007 No.183.
19. The EU Common Strategy on Ukraine, adopted by the Council (Helsinki, December 11, 1999). Presidency Conclusions, Helsinki European Council, point 56, OJ 1999, L. 331/1.

Appendix 7

Duties of the the State Veterinarian and Phytosanitary Service of Ukraine

The assigned duties of the SVPS of Ukraine are the following:

- maintaining the state register of applications for registration of rights to plant varieties (*Register of Applications* in electronic and paper forms), the state register of patent holder's rights to plant varieties (*Register of Patents* in form of a laced paged book), the state register of the plant varieties suitable for distribution in Ukraine (*Register of the Plant Varieties* announced through the issue of the Catalogue of Plant Varieties Suitable for Distribution in Ukraine (Clause 3 of Resolution on the State Register of the Plant Varieties Suitable for Distribution in Ukraine, 2003) and maintaining the registry of applications, rights to plant varieties, maintaining plant varieties (Clause 4 (101) of Provisions on the State Veterinarian and Phytosanitary Service of Ukraine, 2011). To be precise, the Register of Patents and the Register of Applications are administered by the State Service for Protection of Rights to Plant Varieties of Ukraine (SSPRPV) (Clause 1.2. of Resolution on the State Register of the Applications for plant varieties, 2003). So, the SVPS defines measures for legal protection, for instance, through description of a set of features of the relevant variety (Articles 1, 10(4) Law of Ukraine "On Protection of Rights to Plant Varieties"). The SSPRPV maintains the registers. The SVPS of Ukraine maintains *the Register of the Representatives on the Intellectual Property Rights to Plant Varieties* (Clause 5 of the Provisions on the Representatives on the Intellectual Property Rights to Plant Varieties, 2002), too;
- ensuring the publication of official data about filed applications, granted patents to plant varieties and certificates of authorship of plant varieties, issuing the Register of the Plant Varieties suitable for distribution in Ukraine (Clause 4 (102). Provisions on the State Veterinarian and Phytosanitary Service of Ukraine, 2011, Clause 3 of Resolution on the State Register of the Plant Varieties Suitable for Distribution in Ukraine, 2003);
- control of compliance with the requirements to meet the established standards to pedigree (genetic) resources (Clause 4 (109) of Provisions on the State Veterinarian and Phytosanitary Service of Ukraine, 2011);
- control of economic activity in the sphere of pedigree work in livestock breeding dealing with the production of pedigree (genetic) resources, preservation of pedigree (genetic) resources, trade of pedigree (genetic) resources, conducting genetic examination of origin and

anomalies of animals (Clause 4 (111) of Provisions on the State Veterinarian and Phytosanitary Service of Ukraine, 2011).

The order of maintaining the State Register of the Intellectual Property Rights to Plant Varieties, granting of patents of Ukraine to plant varieties and their certified copies, the form of patent are all established by the Resolution on the State Register of the Intellectual Property Rights to Plant Varieties and Granting of Patents to Plant Varieties in Ukraine, approved by the Order of the Ministry of Agrarian Policy of Ukraine No. 390 of December 13, 2002. Information about the variety is also included in the Register of Varieties after the SVPS has taken the decision on its state registration, accomplishment of the state registration of the rights to varieties and payment of the necessary charges, which is made by the applicant (Clause 4 of Resolution on the State Register of the Plant Varieties Suitable for Distribution in Ukraine, 2003).

Appendix 8

Classification of IPRs to GMAPs in the Ukrainian law

1. *Personal non-proprietary intellectual property rights to the variety of plants, animal breed evidenced by the state registration ("authorship rights").*

An author of a plant variety (selectionist) owns *the rights of authorship*, which are personal non-proprietary rights. It cannot be alienated (transferred), and shall be valid perpetually unless otherwise established by law (Articles 16(4), 37(3) of the Law of Ukraine "On Protection of Rights to Plant Varieties" 1993; Clause 1.3. of Statute of Certification of Authorship for Plant Varieties, approved by the Order of the Ministry of Agrarian Policy of Ukraine of May 28, 2003 No.151; Art.452(1) of CCU).

General legal rule on the *personal non-proprietary rights* of intellectual property holds that they shall be:

1) *the right to recognize* an individual as a creator (an author, a performer, an inventor, etc.) of the appropriate object;

2) *the right to prevent* any encroachment on the intellectual property right that may damage the degnity or reputation of the creator;

3) other personal non-proprietary rights of intellectual property established by law" (Art.423 of CCU).

2. *Proprietary intellectual property rights to the variety of plants, animal breed evidenced by the patent.*

According to Art. 424 (1) of CCU, *proprietary intellectual property rights* include the following set of rights:

1) the right to use an object of intellectual property right;

2) the exclusive right to allow others to use an object of intellectual property right;

3) the exclusive right to hinder the unlawful use of an object of intellectual property right, including to prohibit such use;

4) other proprietary rights of intellectual property established by law.

If personal non-proprietary rights have non-material nature, the proprietary rights to IP concern material issues. Art. 423 (4) of CCU contains a more precise definition: "Personal non-proprietary rights of intellectual property *cannot be alienated (transferred),* except for the cases established by law" (Art. 423 (4), 425 (1) of CCU, Art. 37 (3) of the Law "On Protection of Rights to Plant Varieties", 1993). As it is stated in Art. 419 (1) of CCU, personal non-proprietary rights to intellectual property and proprietary right in an object do not depend on each other. Transfer of one of the rights does not mean transfer of the other right (Art. 419 (2,3) of CCU). At the same time, proprietary IPRs can be supplemented by personal non-proprietary rights. Proprietary IPRs are originated with existence of personal non-proprietary rights to the object. In some cases, personal non-proprietary rights of IP can belong to one person and proprietary IPRs to another person. For instance, in case of creation of the GMPs by a scientist and its patenting by the research institute in its name.

3. *Proprietary intellectual property rights to disseminate the variety of plants, animal breed evidenced by the state registration.*

"The right to disseminate the variety of plants or animal breed shall be valid from the date following the date of its state registration and shall be *in effect perpetually*. Validity of the exclusive proprietary intellectual property rights to the variety of plants, animal breed can be early terminated or renewed in the cases and per the procedure established by law" (Art. 488 (5),(6) of CCU).

Appendix 9

Liability related to GMPs (from the Code of Administrative Offenses of Ukraine, 1984)

Number of Article of the Code of Administrative Offenses of Ukraine	*Crime*	*Liability and Fine*
Art. 51-2	*Infringement of rights to the object of IPRs*	from 10 to 200 times the personal exemption of the citizens + confiscation of the illegally manufactured products and equipments, and materials used for production.
Art. 42-3	Production, storage, transportation or sale of food or raw food contaminated with microorganisms or other biological agents, biologically active substances or products of biotechnology over the allowed limits	a) for citizens: from 1 to 12 times the personal exemption (non-taxable minimum income) with a confiscation of the goods or without, b) for officials: from 6 to 25 the personal exemption (non-taxable minimum income) with a confiscation of the goods or without it.
Art. 83-1	*Violation of the legislation on a plant protection* means: 1) the spread of the harmful organisms due to a violation of technology to grow the agricultural and other plants; 2) exercise of the plant protection in not environmentally way; 3) concealment or provision of false information about the threat to crops, tree plantations, other vegetations from the open and protected ground, and plant products from the harmful organisms; 4) The import into the territory of Ukraine and sale of the plant protection products, as well as materials and raw materials for their production, which have not passed state examination and registration; 5) avoidance of presentation or not presentation of the plant protection products for their inspection, investigation; 6) non-compliance with the requirements of the legal acts on the protection of plants, resulting in damage, deterioration	entail *a warning or impose a fine,* a) for citizens: from 5 to 10 times the personal exemption (non-taxable minimum income), b) for officials: from 10 to 18 the personal exemption (non-taxable minimum income).

	of the quality of plants and plant products, and pollution of the environment	
Article 90-1	Failure to comply with rules and regulations on the creation, production, storage, use, destruction, removal, disposal of microorganisms, biologically active substances and other products of biotechnology: 1. Failure to comply with the rules and regulations in the process of creating new strains of microorganisms, biologically active substances and other products of the biotechnology, 2. Failure to comply with the rules and standards of environmental safety in the production, storage, transportation, use, disposal, removal, disposal of microorganisms, biologically active substances and other products of the biotechnology	1. From 5 to 8 times the personal exemption. 2. a) for citizens: from 5 to 8 times the personal exemption, b) and officials - from 7 to 10 times the personal exemption.
Article 91-1	Failure to comply with the requirements on the environmental safety in the implementation of discoveries, inventions, utility models, industrial designs, innovations, new technology, techniques and systems, substances and materials	a) for citizens: 3 to 5 times the personal exempti, b) for officials - from 4 to 7 times the personal exemption.
Article 188-12	Failure to comply with the legal requirements of the specially authorized executive body in the field of plant protection	a) for citizens: from 5 to 10 times the personal exemption, b) for officials: from 10 to 18 times the personal exemption.
Article 164-3	Unfair Competition: 1. Illegal copying of forms, packaging, exterior design, as well as imitation, copying, direct reproduction of a product of another entrepreneur, unauthorized use of the latter's name, 2. Receipt, use, disclosure of trade secrets and other confidential information damaging the reputation or property of another entrepreneur	1. from 30 to 44 times the personal exemption of citizens with confiscation of manufactured products, means of production and raw, or without it. 2. from 9 to 18 times the personal exemption of citizens.
Article 107-1	Violation of law on livestock breeding	a) for citizens: five to ten times the personal exemption of citizens, b) for officials - from 30 to 50 times the personal exemption.

Norwegian University
of Life Sciences

Postboks 5003
NO-1432 Ås, Norway
+4767230000

www.nmbu.no