



FACULTY OF LAW  
University of Lund

Ida Agering

Why compulsory licensing of  
genetically modified food will not  
be a possible way of fighting  
world hunger

Master thesis  
20 points

Hans Henrik Lidgard

Intellectual Property

2007

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# Summary

Over 800 million people in the developing world are affected by chronic hunger today. Hunger reduction is necessary for accelerating development and poverty reduction. It has been argued that genetically modified food (GM food) could be the solution to the third world hunger problem. Scientific progress in modern biotechnology has resulted in new medical treatments and vaccines. Biotechnology in the field of agriculture might lead to increased food security, decreased pressure of land use, sustainable harvest in unfavourable environments and reduced use of water and agrochemicals in agriculture. GM crops are, however, results of research and development in the developed world, inaccessible in the developing countries.

This thesis examines the possibility to apply the same legal tools for GM food, as are designed for the compulsory licensing of pharmaceuticals that fight the AIDS crisis. An analysis is also made concerning the appropriateness of biotechnologies in the developing world.

The IPRs available concerning GM food are either patents or plant variety protection. Plant varieties are excluded from patentability, as well as the essentially biological processes for the production of plants. The objective of plant variety protection is to stimulate the development of new plant varieties by ensuring the plant breeders a certain economic benefit of the breeding. The scope of protection is fairly similar in both systems, although the breeder's rights exception is broader in the case of plant variety protection. Compulsory licences of GM food are allowed by the TRIPS Agreement (with clarifications made in the Doha Declaration) and may give access to a patented material for research and breeding, on grounds related to public interest, national emergency or protection of the environment. If a compulsory licence agreement is issued, adequate remuneration must still be paid to the patent holder. Few compulsory licences have been issued for essential AIDS medicines, to this date, implying that very few, if any, compulsory licences on GM food will be granted in the foreseeable future. One reason is that the Doha Declaration was designated to combat health problems due to epidemics, by facilitating the access to medicines. Concerning supplying the developing world with GM food, the question is not access per se, but a choice between GM and non-GM food. There is no justification for choosing GM food, at this moment.

Biotechnology may in the future, under the right circumstances, adapted to local conditions that favour small-scale farmers, increase farm income and lower food prices. Trade may contribute to hunger reduction and poverty alleviation, but market infrastructure, domestic institutions and policy reforms and safety nets are required to ensure the benefits. Public investments in, for example in domestic agricultural research and education, are essential for agricultural growth and sustainable development.

# Abbreviations

AIDS	Acquired immune deficiency syndrome
Bt	Bacillus thuringiensis
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
DNA	Deoxyribonucleic acid
DUS	Distinctiveness, Uniformity, Stability
EC	European Community
EPA	United States Environmental Protection Agency
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FAO	Food and Agriculture Organisation
FAQ	Frequently asked questions
GM	Genetically modified
GMO	Genetically modified organism
HIV	Human immunodeficiency virus
IPR	Intellectual Property Right
MAS	Marker-assisted selection
NGO	Non-governmental organisation
OECD	Organisation for Economic Co-operation and Development
PBR	Plant breeder's right
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNDP	United Nations Development Program
UPOV	International Union for the Protection of New Varieties of Plants
US	United States
USPTO	United States Patent and Trademark Office
WHO	World Health Organisation
WTO	World Trade Organisation

# 1 Introduction

## 1.1 Background

*What has struck me is that throughout my examination of the various detailed regulatory arguments about GM food and crops on both sides of the Atlantic I have rarely seen any references as to whether or not GM crops can (or cannot) help solve world hunger. (...) Yet, in general popular debate, this argument features predominantly. Perhaps the 'GM crop will alleviate world hunger' storyline serves as a general rhetorical rejoinder to green claims that GM crops are the product of corporate villains who care only for profits.*  
– Dave Toke

This comment<sup>1</sup> made by Dave Toke, a researcher and lecturer in politics and sociology at the University of Birmingham, UK, displays several of the issues concerning genetically modified food (GM food). It involves both technical areas such as biology and ecology, regulatory areas such as law and international politics, as well as social focused areas such as sociology, ethics and health.

The questions that arose when I started learning about the subject were many: What exactly is GM food; where does it come from; who is developing it and why; how can we use it; what are the risks; in whose interest does it exist, and above all, is it true that it could possibly be a way of fighting world hunger? My first thoughts were in reference to the mechanism of granting compulsory licences on HIV/AIDS medicine with anti-retroviral effect, in order to offer these for a reasonable price, in developing countries where the people suffering from HIV/AIDS are poor and have no possible means of purchasing these medicines at market price in the developed world. This system is constructed with the pharmaceutical industry in mind, but is it applicable to other areas?

Considering the seemingly endless possibilities with gene modification, one realises that this could become a way of helping the developing world with cultivation of crops, in the production of food under severe climate conditions, or to increase nutrition values. Suppose researchers develop a kind of wheat that does not need as much watering as “normal” wheat, or wheat with high levels of vitamin A or protein. That could definitely solve the food supply problems, providing that this technique actually would reach the farmers and food producers in the third world. At the same time, consumers are uneasy by the fact that something no longer is natural.

A basic humanitarian question is: Should we fight starvation? Probably no one would answer no. The more complex questions are *how?* and *with what means?*. Nothing yet has given a fully satisfying result.

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<sup>1</sup> Toke, *The Politics of GM Food*, 2004, p. 7.

## 1.2 Purpose

My aim is to study the possibility for genetically modified plants and crops to be subject to compulsory licensing as a way of fighting starvation in the developing world. To find a complete and reasonable answer to this question, several discussions have to be pursued, like pieces of a big puzzle, to be able to see the whole picture in the end. There is of course the technical issue of compulsory licensing, with a natural starting-point in the relevant articles of the TRIPS Agreement. This question is inevitably affiliated with the question of patentability, more exactly concerning modified crops, plants and other types of food. There is also the practical and social issue of the use of such modified plants. It is one thing to conduct research and development on gene modification in a closed laboratory, it is another to grow, spread and sell, and *eat*, the offspring of these experimentations. It is interesting to look into the differences in opinion regarding this issue, which implies a controversy in third world aid of this kind. Apart from having legal aspects, this question is of an ethical, or rather a moral, matter.

## 1.3 Delimitations

GMOs refer both to plants and other living organisms. My interest lies in plants, crops and other types of vegetation that can be processed into food, thus excluding all living species such as animals and micro-organisms from my study. I will not extensively discuss pros and cons of the existence of gene patents. I will look into the ongoing discussion between the members of the global community in the extent to which it can help us understand the ethical, moral and practical problems related to food, biotechnology and IPRs in relation to developing countries. I intend to keep a European perspective and I will not focus so much on the legal systems specific to the US.

## 1.4 Method

Since the question is multiplex, and spans over several fields of discussion, I will be using several methods in my study. In Europe, as the typical example and representative for the developed world, a normative system based on legal rules and laws is used, creating the skeleton of society. In Africa, as the symbol continent of the developing world, not only the legal system is of normative value; social, mythological and relational rules have just as much normative value. The perspective when studying the legal system in Africa must be broader since the written law is only one part of the culture. Rules must be studied in a bigger social, cultural, economic and religious context. Therefore, in the discussion on the morality and ethical correctness of compulsory licensing of genetically modified plants, both a philosophical method and a law and sociology method is used.



The analysis of the convention wording and interpretation of laws and regulations is made with a traditional legal approach, since convention texts and international law often are created in the developed world. In addition hereof, the significance and consequences of these international conventions and treaties, will take into account the different setting of the developing world, of both cultural and practical importance. Inconsiderate of my doubts about the existence of what you could call a third world method – it might merely be a perspective – that is what will constitute part of the frame in my discussion.

## **1.5 Material**

There are great amounts of literature published on all the possible aspects relating to biotechnology and globalisation. I base my thesis both on articles found in different international archives and web based libraries, on books, as well as on publications from governmental and non-governmental organisations (mainly those under the auspices of the United Nations). The diversity of perspectives gives an interesting and more complete picture, yet at the same time, the quantity of information makes it hard to condense in a fair manner. The same concerns the legal texts. There are many treaties and conventions, as well as international, bilateral and regional agreements of different magnitude. I will focus on the most important ones that have a significant impact on the state of biotechnologies in the world. No specific author or work has been of greater importance than the other, in fact the majority of what I have read has been excellent. If I were to recommend something in particular, it would be the reports and all the information published by the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO).

## **1.6 Disposition**

To give the proper setting of my subject, I open with the question of GM food in general. I examine what it is, why we have it and why we would not want to have it. Then, I continue with the technical aspects of legally protecting GM food, in different ways. I investigate the conditions for the grant of patents and protecting plant varieties. Having those technical and legal frames, I examine, first, the applicability of the compulsory licensing regime, then, the appropriateness of the same. In the last part of the thesis I look at different, both social and practical, aspects making the this kind of third world aid controversial, and finally, I make an attempt at drawing some closing conclusions on the matter, giving a prospect of what we can expect of the future development of the area of study.

## 2 Biotechnologies in the food sector

Each chapter of my thesis has a specific focus, where the different aspects are important for the understanding of the situation as a whole. To set the scene, I start with an introductory chapter on food and gene modification, at the grass roots, both figuratively and literally speaking.

### 2.1 GM food – the alchemy of our time

A genetically modified organism (GMO) is the result of a change of the DNA of an organism, animal or plant, by combining DNA molecules from different sources into one molecule. The first successful GMO laboratory experiments were made in the early 1970s, although cross-breeding of both plants and animals is an older phenomenon. Modern biotechnology is different since researchers take a single gene from a plant or an animal cell and insert this cell in another plant or animal cell to give it the desired characteristics that cannot be obtained with traditional cross-breeding.<sup>2</sup> Most of the genetically modified crops (GM crops) cultivated today are pesticide resistant or resistant to certain insect attacks. Researchers are currently trying to develop plants that are resistant to drought, frost, mould and different viruses, as well as plants with higher nutrition values, lower levels of allergens (causing allergies) and other toxics, faster growth, higher yields and changes in flavour, shape and appearance. Over 90 percent of commercially cultivated GM crops today are, however, developed to increase the yield per acreage. The products of higher consumer values are expected to become more important in the future.<sup>3</sup>

It is a common perception that people in general have a negative attitude towards genetically modified food, so called GM food. The fact that something no longer is natural, genetically speaking, makes the consumer uneasy and it is true that the long-term effects of GM foods, on the environment and on humans remain uncertain.

The European Union (EU) has taken a “go slow” approach with respect to approving GMOs, whereas the United States and Canada have taken a much more relaxed position towards them. This difference in approaches between North America and Europe has become apparent especially in the last years ongoing debate.<sup>4</sup> However, the situation has, historically, been different. The European environmentalist mobilisation developed late, compared to

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<sup>2</sup> Cartagena protocol on Biosafety, FAQ on the Biosafety Protocol, question 1, <http://www.biodiv.org/biosafety/bch-faqs2.pdf> (retrieved on 2007-02-07).

<sup>3</sup> Hellstadius, *Patent eller växtförädlarrätt?*, 2001, p. 11.

<sup>4</sup> Clapp, *Unplanned Exposure to Genetically Modified Organisms, Divergent responses in the Global South*, *The Journal of Environment & Development*, Volume 15 Number 1, March 2006 3-21, <http://jed.sagepub.com> hosted at <http://online.sagepub.com>

the US, generally speaking. In the 1960s and 1970s, environmental public policy in general was more radical in the US than in the EU. The establishment of the Environmental Protection Agency (EPA) and many public interest activist groups of that time, was to a large extent a result of political activism (anchored by antiwar movements during the war in Vietnam). The US took action for example against ozone-eating chlorofluorocarbons in the 1970s while the equivalent did not happen in EU until in the 1980s.<sup>5</sup> Since the 1980s the see-saw has shifted, either with the US environmental public policy becoming weaker, or with EU having a relatively more risk-averse approach with policies developing at a higher speed and becoming more extensive. Green parties appeared and grew stronger and different environmental campaigns spread. It is during this time that regulations on GM crops were formulated, at a time where US environmental policy was becoming more conservative and European policy was becoming more radical on environmental issues.<sup>6</sup> As a contrast, or to complete to this picture, the strength of religious groups in US politics has prevented stem cell research in the US, while it is permitted in some EU countries. Although the particular question of stem cell research is related to the discussion of ethics and the desired development of genetics as such, it has fairly little to do with environmental issue that is in question with GM food.<sup>7</sup>

The dispute between the US and the EU has been fought within the WTO, but trade protection has little to do with the EU's refusal to consume GM food products and licence GM crops. It is not the European farmers but the consumers that are against it.<sup>8</sup> This consumer resistance is not to underestimate as a power. In India, where the Hindus are vegetarians, many are worried about animal genes accidentally turn up in vegetables and sale of GM food is therefore illegal.<sup>9</sup>

## 2.2 What is food?

Food is the very essence of us, we need it to stay alive. The attitude towards food is different in different parts of the world. Food can be seen as a substance, a quantity, crucial for our survival, but it can also be a bearer of gastronomic culture, something of quality, to eat for pleasure. In Europe, for instance, the traditional cuisine of a country creates a national sense of identity, dear to its people.<sup>10</sup> The Americans, by contrast, see themselves as a melting pot of many cultures and since the last decades, they tend to eat out rather than at home, while the Europeans traditionally have preferred cooking at home. As a reaction to the American fast food and junk food culture, a slow food movement was created in Europe, focusing on the quality of food and the relationship that we establish with food and on

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<sup>5</sup> Toke, p. 104-106.

<sup>6</sup> Toke, p. 104-106.

<sup>7</sup> Toke, p. 104-106.

<sup>8</sup> Toke, p. 209.

<sup>9</sup> Toke, p. 29.

<sup>10</sup> Toke, p. 142.

savouring with pleasure and awareness. With fast food there is no time to enjoy and find out about its history and origin. Slow food accentuates a link both to the past and to a specific region or place. These differences in food culture could explain why GM food has not met the same acceptance in Europe as in the US. GM food is a product of the latest technology, without a history and without a specific place of origin.<sup>11</sup>

## **2.3 The appropriateness of new biotechnologies compared to conventional methods**

The benefits of modern biotechnology are advances in the field of medicine, including new medical treatments and vaccines, as well as in the field of agriculture, including increased food security, decreased pressure of land use, sustainable harvest in unfavourable environments and reduced use of water and agrochemicals in agriculture.<sup>12</sup> There are undisputedly benefits with new biotechnologies. The successive question is whether the advantages outweigh the disadvantages, such as the unpredictability of a long-term use and the effects on humans, animals and our environment.

### **2.3.1 Public health concerns**

Long-term consequences of consumption of GM food are still uncertain. Therefore, it is more appropriate to discuss the risks than the documented effects of GM food consumption. There are two different types of impacts of GM foods on human health. The first is the effect of consuming a GM product and the other is the effect of GMOs through environmental impact, in other words, the direct or indirect effect on human health that the agricultural practices have. Neither GM food, nor non-GM food is guaranteed to be completely safe and tests of edible GM crops compared with its non-modified equivalent have in many cases not shown any differences in food quality are found.<sup>13</sup>

The potential direct health effects of GM food are generally comparable to the well-known risks associated with conventional foods. These include, for example, the presence of allergens or toxics, or the quality and microbiological safety of the food.<sup>14</sup> An uncertainty related to GM food, is that gene expression (effect) is subject to environmental influences, both in conventional and GM crops. Environmental conditions such as drought or heat can stimulate some genes, turning the expression up or down.<sup>15</sup>

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<sup>11</sup> Toke, p. 143.

<sup>12</sup> Cartagena protocol on Biosafety, FAQ on the Biosafety Protocol, question 5.

<sup>13</sup> Ruane and Zimmermann Forum coordinators, FAO, *Agricultural Biotechnology for Developing Countries – Results of an Electronic Forum*, 2001, Crop sector conference, Chapter 2 (hereinafter referred to as “Crop sector conference”).

<sup>14</sup> Food Safety Department, WHO, *Modern Food Biotechnology, Human Health and Development: an Evidence-Based Study*, 2005, p. 13.

<sup>15</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 14.

Another concern is the potential allergenicity caused by GM food. The major food allergens are proteins and the allergic reactions to traditional foods are well-known. But the application of modern biotechnology to crops risk to make food less safe if the added protein proves to cause an allergic reaction once in the food supply.<sup>16</sup>

The GM crops producing toxins of the soil bacterium *Bacillus thuringiensis* (Bt), *could* be harmful or allergenic when eaten by humans. Crystal proteins from Bt are toxins that kill insects feeding on the plant by binding to and creating pores in their midgut membranes. Some argue that there is no evidence that ingestion by humans of plants producing the toxin is safe. On the contrary, others argue that most proteins, including Bt toxins, are denatured by the acidity in a human stomach and that it is unlikely that the toxin endangers human health, although caution is always recommended.<sup>17</sup>

In some cases, a certain GM crop has been approved for animal feed and industrial uses, but not for human consumption. One example is Cry9C, a heat and digestion resistant Bt toxin transferred to a GM corn, that was under consideration for use as human food in the US at first. Some argue that the mere fact that this specific GM crop, finally, only was approved for animal feed and industrial use, indicates that the regulatory system in the US is working.<sup>18</sup>

I have brought fourth a small selection of the many aspects of and arguments about the effects of GM food on humans. According to a study published by the Food and Agriculture Organization of the United Nations (FAO), GM foods currently available on the international market have undergone risk assessments and are not likely to present risks for human health more than their conventional equivalents.<sup>19</sup> There have been a few incidents in the past where people have fallen very ill after eating GM food, and I predict that there are more to come, especially since GM food is gaining ground, but persuasive voices on both sides of the discussion table will probably remain.

### **2.3.2 Environmental and biodiversity impact**

Modern biotechnology is still a new field and the results of interaction with various ecosystems are not yet known. The risks are that the ecosystems and the biodiversity will change when the characteristics of the target species have been modified, for example competitiveness and toxicity features. There is also the question of stability of the inserted genes and the risk that the GM crop unintentionally transfers a gene into another (wild) crop.<sup>20</sup> It has, on the other hand, been suggested that biotechnology could have a positive impact on biodiversity in the environment, by increasing the

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<sup>16</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 16.

<sup>17</sup> Crop Sector Conference, chapter 2.

<sup>18</sup> Crop Sector conference, chapter 2.

<sup>19</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 24.

<sup>20</sup> Cartagena protocol on Biosafety, FAQ on the Biosafety Protocol, question 6.

amount of food produced per unit of land area and thus reducing the need to use forest or natural habitats for additional food production in the future.<sup>21</sup> The introduction of GM crops has also given a positive effect on the environment that also concerns the health of farmers. In many Asian countries, chemical insecticides are used in a large scale, which affects the people working with in the fields and being exposed to these chemicals every day. Stories have been on the news about the how harmful the cotton industry is for the workers. Pesticide-resistant GM crops could reduce the levels of pesticides and insecticides, some have argued, although I do not see the logic in why pests and insects would become less interested in a crop only because the crop is resistant to some specific chemicals. One way that human health has been improved is through the decreases in the amount of energy use, toxic and solid wastes in the environment, with the production of chemicals or enzymes from contained GM micro-organisms (chemicals, pharmaceuticals or food additives).<sup>22</sup>

There were some initial concerns about so called genetic pollution of transgenic DNA into traditional landraces of maize in Mexico, as a result of findings of transgenic DNA in such landraces in 2000. At some point, as alarmingly high levels as 10-15% of the non-GM maize were said to have been contaminated by the unwanted gene. Recently published results from samples taken during a broad, systematic survey in 2003 and 2004 in the same region, showed no trans-genes in these landraces. Still, the potential for this type of gene pollution remains a possibility in the future.<sup>23</sup>

There is also a risk that pest-resistant GM crops accelerate the development of making pests resistant to the specific pesticides. Major companies in the field of biotechnology are already conducting research to develop successors to the pest-resistant GM crops.<sup>24</sup>

Currently, the Cartagena Protocol on Biosafety (CPB) of the Convention on Biological Diversity is the only international regulatory instrument, which deals specifically with the potential adverse effects of GMOs on the environment, taking also into account the effects on human health.<sup>25</sup>

### **2.3.3 The need for balanced information**

The question of GM food and the compulsory licensing thereof embodies many discussions. I agree with Toke that it is hard to give an objective description in a controversial topic like this without making clear the assumptions that guide this objectivity.<sup>26</sup> Different interest groups focus on different concerns about GM food, since they might make entirely different priorities, and this is important to bear in mind while learning about the

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<sup>21</sup> Crop Sector Conference, chapter 2.

<sup>22</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 19.

<sup>23</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 19.

<sup>24</sup> Crop Sector Conference, chapter 2.

<sup>25</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 20.

<sup>26</sup> Toke, p. 12-13.

many aspects of GM food and compulsory licensing. It is never enough to read what one author has to say and think of that as the right opinion, most authors emphasise different aspects, maybe in a subtle or unconscious way. The biotechnology industry is mostly supported economically and encouraged by corporate powers and the interest groups hostile to the development are mainly two: environmental groups and human health concerned groups. Radical greens, for instance, rule out GM crops almost by definition because they have a strategic objection to GM crops.<sup>27</sup> I will try to give a balanced perspective, both in the technical and more ideological analysis. I have, in my thesis, made my priorities too, but I find that it has a purpose to express a position or be of a certain opinion, to force the reader to react and hopefully want to learn more to form an opinion of him or herself. Some have argued that one reason for the debate being so polarised might be that GM crops have been grown commercially without sufficient consultation and before there was a thorough investigation of the potential problems. An observation is also that the political party in power often influences governmental organisations, while NGOs most often oppose biotechnology.<sup>28</sup> There are evidently also organisations aiming to bring the two sides together and spreading as correct information as possible, taking the FAO as an example.

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<sup>27</sup> Toke, p. 13.

<sup>28</sup> Crop Sector Conference, chapter 2.

# 3 Patents on biological materials

In the following two chapters (3 and 4) I illustrate the two different types of legal protection system that come into question in the case of GM food: the traditional patent system and the plant variety protection (or the plant breeder's right – PBR). After a clarification of the differences between those two types of legal protection is made, I will continue with an analysis of the compulsory licensing in the two areas, in chapter 5. Each protection system has its own prerequisites, scope of protection and protection purpose.

## 3.1 Legal and ethical aspects of bio-patenting

We live in an information society and a knowledge-driven global economy where ownership and the protection of this knowledge becomes more and more important. The patent system was developed a long time ago for protecting inventions in the mechanical era. The biotechnology field is growing, entailing large corporate investments, which is leading to an increasing demand for legal protection of the research results. Legal protection of biological material is, however, a controversial matter and there is a strong opinion against monopolising biological material. One fear is that legal protection of plants lead to an unequal situation between the developing and the developed countries, since farmers in developing countries could become dependant on multinational corporations if the possibility is given to legally protect agricultural products.<sup>29</sup>

Patent protection in the field of biotechnology has also brought new ethical considerations into light and the evolution of the IPR regimes in the 20<sup>th</sup> century has been characterised by three phenomena: the broadening of existing rights, the creation of new rights and the progressive standardisation of the basic features of IPRs.<sup>30</sup> The system is facing some difficulties in applicability with the introduction of modern biotechnologies, with respect to the scope of protection and the definition of what is patentable.<sup>31</sup>

### 3.1.1 International and legal instruments

The patent system is the subject of several international agreements. The most important one on the international level, is the WTO Agreement on

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<sup>29</sup> Hellstadius, *Patent eller Växtförädlarrätt?*, 2001, p. 12.

<sup>30</sup> Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge*, 2004, p. 21.

<sup>31</sup> Thumm, *Patents for Genetic Inventions, a Tool to Promote Technological Advances or a Limitation for Upstream Inventions?*, *Technovation* 25, 2005, p. 1410.



Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement applies to all the members of the WTO and promotes the standardisation of national IPR regimes. The Agreement is considered highly beneficial for science-based corporations seeking to expand their sales in developing countries and has been subject to criticism for the high standards of protection, which is not appropriately adapted for developing countries that are the net importers of technologies and IP-protected goods. These countries would probably benefit more from lower standards at the present time.<sup>32</sup> The member states of EU<sup>33</sup> are also bound by the European Patent Convention (EPC). The purpose of EPC was to create a centralised organisation for granting patents in Europe, making the process less expensive.

### 3.1.2 Patents on genes

Legal protection of genes and biological material is far from uncontroversial and a strong opposition comprising activists, environmental groups as well as the general public has operated along side the researchers and biotechnology companies. The dangers and possible effects of the technical development are important issues to discuss, as well as the desirable direction of the research.<sup>34</sup>

A new problem of drawing a line was raised with the possibility of patenting biological material, above all, human genes. Genes are indeed chemical compounds but the DNA-segment is a specific group of complex chemical compounds, placing genetics on an equal footing with chemistry in practice. The EPO seem to have been extensive in its definition on patentability of biotechnological creations. However, there are reasons why these chemical compounds constituting genes should not be on equality with other types of chemistry. There is a need to keep genes free, enabling important research in the field. It might, in this aspect, be appropriate to limit the patentability on genes to the mere *use* and exclude the gene itself from patentability.<sup>35</sup> European patent case law is considered to have granted patents too broad within the biotechnology field. The Directive 98/44/EC on the legal protection of biotechnological inventions<sup>36</sup> (the Biotech Directive) makes specific demands on the description in the patent application of the function of the gene for which the patent is filed. A different function of the same gene is considered an independent invention.<sup>37</sup>

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<sup>32</sup> Dutfield,, p. 25.

<sup>33</sup> Together with Lichtenstein, Switzerland and Monaco.

<sup>34</sup> Hellstadius, p. 12.

<sup>35</sup> Dutfield, p. 29.

<sup>36</sup> Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions.

<sup>37</sup> Koktvedgaard and Levin, *Lärobok i Immaterialrätt*, 2004, p. 235; See also recital 25 of the Biotechnology Directive.

## 3.2 Patentability requirements

The fundamental criteria of patentability, set forth in EPC art 52.1 are three. The *invention* (including an inventive step) must have an *industrial application* and be *novel*. The problem appears at the prerequisite novelty concerning genes and chemical compounds. The traditional separation between an invention and a discovery remains but international patent doctrine and case law have changed. The international trend during the 1960s seemed to favour the chemical industry as strong patents as possible. Thereby the dividing line separating invention from discovery began to dissolve in this area. What was found patentable was the production process, the mere existence and its structure, albeit the existence of the chemical compound in nature.<sup>38</sup>

The British Nuffield Council on Bioethics, which is an independent body examining ethical issues raised by new developments in biology and medicine, published a discussion paper in 2002 concerning issues of bio-patenting. The authors conclude that DNA patents should be examined in the light of the criteria for inventiveness and industrial application (also called utility). The test of novelty is manageable, unlike the tests of inventiveness and industrial application, which are both more problematic. Since the use of computers to identify genes has increased, thus failing to meet the criterion of inventiveness, the suitability of patenting of DNA sequences should have diminished.<sup>39</sup> They also point to the fact that the EPO sets a higher threshold for inventiveness than the USPTO, which is appropriate. Concerning industrial application, some positive evidence that the DNA sequence has such a claimed application should be required and the application in question should be more than a biological function, since a biological function merely is a description of nature and not a practical industrial application in the usual sense applied to an invented product. They conclude that in future, the granting of DNA patents should rather become the exception than the norm.<sup>40</sup>

There are different types of patents: product patents, process patents and use patents. A product patent protects an object or a phenomenon; a process patent protects the procedure to produce; and a use patent protects a new use of an already known product. The system seeks a balance between researchers, companies and inventors, on the one hand, and the public interest on the other.

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<sup>38</sup> Levin, p. 235.

<sup>39</sup> Nuffield Council on Bioethics, *The ethics of patenting DNA*, 2002, p. 69. <http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf> (retrieved on 2007-02-08).

<sup>40</sup> Nuffield Council on Bioethics, p. 70.

### 3.3 Exclusion from patentability

Even if the patentability requirements are met, a patent might still not be granted. Both the TRIPS Agreement and EPC contain provisions of exclusion. Article 27.2 TRIPS and Article 53 (a) EPC exclude from patentability inventions that are contrary to ordre public or morality. The terms “ordre public” and “morality” are not defined, although the TRIPS Agreement as a whole take consideration to human, animal or plant life or health and the environment. Legal experts argue that the exclusion in TRIPS should be applied narrowly and on a case-by-case basis rather than to broad classes of patents, such as life forms in their broadest sense.<sup>41</sup>

As I have mentioned, the concept of invention is a key questions for the possibility to obtain patent protection. An invention merits protection as a result of the inventors research and creation work, while a discovery does not, since the knowledge was there all along, waiting for someone to find it. An invention is produced within a technical field and has to be novel. Discoveries shall not be regarded as inventions and are excluded from patentability, according to EPC art 52.2 (a).

#### 3.3.1 The concept of plant variety

Within the EU, the Biotech Directive addresses the patentability if living matter in general, but excludes plant and animal varieties in Article 4.1 (a). Article 53 (b) EPC, states that plant or animal varieties or essential biological processes for the production of plants or animals shall not be granted a European patent. This corresponds to the wording of article 27.3 (b) of the TRIPS, allowing the exclusion of plants and animals other than micro-organisms, and essentially biological processes for their production other than non-biological and micro-biological processes. Plant variety protection in Europe is instead assured by the plant breeder’s right (PBR) regulations. However, as we will see in chapter 4, separating patentable plants from non-patentable plants is a problematic task.

#### 3.3.2 The research exception

Many countries allow researchers to use a patented invention for research, in order to promote advances in science and technology. The legal grounds for the research exception is set forth in Article 30 of TRIPS. In addition, some countries allow the manufacturers of generic drugs to use the patented invention to obtain marketing approval from public health authorities, without the patent owner’s permission and before the patent protection expires. In this way, the generic producers can market their versions as soon as the patent expires. A case with Canada was settled on this matter and a in a report adopted in 2000, a WTO dispute settlement panel confirms this principle and its conformity with TRIPS.<sup>42</sup>

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<sup>41</sup> Dutfield, p. 28.

<sup>42</sup> *TRIPS and Pharmaceutical Patents*, WTO OMC Fact Sheet, September 2006, p. 3.

## 4 Plant variety protection

As mentioned above, under sub-chapter 3.3.1, plant varieties and the biological processes for the production of plants are excluded from patentability in TRIPS, EPC and the Biotech Directive. Explicitly not excluded are microbiological processes or the products of these processes. Plant varieties are not patentable but the products of the processes for the production of plants are patentable, which complicates the situation of drawing an exact line. In the end, it will be a question of how these concepts are being defined and the interpretation thereof. In this chapter I examine the area of plant variety protection and the division between patentable and non-patentable plants.

### 4.1 International agreements and European legislation

The plant variety protection system offers a product protection for a plant variety. The objective of the legislation in this area is to stimulate the development of new plant varieties by ensuring the plant breeders a certain economic benefit of the breeding.<sup>43</sup> There are two types of plant breeding: the traditional plant breeding that has been known and practiced for hundreds of years, and plant breeding through gene modification.

The key international agreements relevant to intellectual property and biogenetic resources in this aspect are the TRIPS Agreement, the International Convention of Protection of New Varieties of Plants from 1961, revised several times, the last time in 1991 (the UPOV Convention); the Convention on Biological Diversity (CBD), and the International Treaty on Plant Genetic Resources for Food and Agriculture (also known as the International Seed Treaty).

Article 27.3 of the TRIPS Agreement allows its members to provide for a *sui generis* alternative to patents for the protection of plant varieties. This *sui generis* system may be defined in various legal forms. Within the EU and specifically referring to plant variety, is the EC Council Regulation No 2100/94 on Community Plant Variety Rights, from 1994, harmonising European plant variety rights. The EC Regulation does not replace national legislation and it is not possible to obtain a double protection with the two systems, one at a national level and another on an EU level.<sup>44</sup>

Internationally, the system for plant breeder's rights in the industrialised world is developed and co-ordinated by UPOV. UPOV has nothing to do

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<sup>43</sup> *Oinskränkt Produktskydd för Patent på Genteknikområdet*, SOU 2006:70, p. 162. [http://www.stockholmbioregion.com/upload/Oinskrankt\\_produktskydd.pdf](http://www.stockholmbioregion.com/upload/Oinskrankt_produktskydd.pdf) (retrieved on 2007-02-08).

<sup>44</sup> Hellstadius, p. 13-14.

with Article 27.3 of TRIPS. However, there are few alternatives, and this is probably why more developing countries are joining UPOV.<sup>45</sup> It is unclear how much space the TRIPS Agreement gives countries to introduce plant variety protection that differs from UPOV and that is adapted to the conditions in developing countries.<sup>46</sup>

In 2004, The International Seed Treaty, which was negotiated under the auspice of the FAO, came into force. The treaty aims to ensure that the plant genetic resources for food and agriculture, which are vital for human survival, are conserved and sustainably used and that benefits from their use are equitably and fairly distributed.<sup>47</sup> The Treaty is closely linked to the CBD (specifically mentioned in the objectives of the Treaty), as it covers the agricultural diversity. With the Treaty, the major food crops shall be kept totally free from patents. The Treaty covers all plant genetic resources of importance to agriculture, but for 64 key food crops, a specific Multilateral System of Access and Benefit-sharing is established, annexed to the Treaty. Benefits are to be shared through information exchange, technology transfer, capacity building, and the mandatory sharing of the profits of commercialisation.<sup>48</sup>

## 4.2 Plant breeder's rights

The preamble of the Biotech Directive expresses the importance of providing a definition of a plant variety in order to ensure the proper functioning of the patent system.<sup>49</sup> The definition in the Biotech Directive refers to the definition in the EC Regulation and had no intention to alter the already established definition. The definition in Article 5 of the EC Regulation is identical to the definition in Article 1 (vi) of UPOV<sup>50</sup>, where the term plant variety is defined as “a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be

- defined by the expression of the characteristics resulting from a given genotype or combination of genotypes,
- distinguished from any other plant grouping by the expression of at least one of the said characteristics and
- considered as a unit with regard to its suitability for being propagated unchanged;”

A distinction is made between general plant varieties and protectable varieties. A plant can be defined as a plant variety, but still not meet the

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<sup>45</sup> Dutfield, p. 70.

<sup>46</sup> De Vylder and others, *The Least Developed Countries and World Trade*, Sida studies No. 5, 2001, p. 140-141.

<sup>47</sup> Article 1 of the International Seed Treaty

<sup>48</sup> Articles 11-13 of the International Seed Treaty.

<sup>49</sup> Recital 9 of Directive 98/44/EC.

<sup>50</sup> The definition of plant variety in Article 2 of the International Seed Treaty is similar and signifies no difference.

specific requirements of obtaining protection.<sup>51</sup> These requirements, which are equivalent in the EC Regulation and in UPOV, are called the DUS criteria: Distinctiveness, Uniformity and Stability. In addition to the DUS criteria, the fourth requirement of novelty is often mentioned.

### **4.2.1 Distinctiveness**

A plant variety needs to be different from other varieties known at the moment of application for registration. Varieties are in other words compared with each other.<sup>52</sup> Article 7(1) of EC Regulation states that a “variety shall be deemed to be distinct if it is clearly distinguishable by reference to the expression of the characteristics that results from a particular genotype or combination of genotypes”. Different guidelines are used when examining a plant variety. Differences can involve the appearance of the plant, as well as characteristics and other distinctive features.

### **4.2.2 Uniformity**

The uniformity requirement establishes how much different individual plants of a variety may vary and still fall within the scope of protection. According to Article 8 UPOV, the uniformity is maintained if the plant is “sufficiently uniform in its relevant characteristics”, while in Article 8 of the EC Regulation uniformity is maintained if the plant is “sufficiently uniform in the expression of those characteristics which are included in the examination for distinctness”.

### **4.2.3 Stability**

Stability is maintained if the plant variety does not change after repeated propagation.

### **4.2.4 Novelty**

For plant variety protection, the concept of novelty is different from the patent system, where the novelty requirement is absolute and unbiased. For plant protection, it is sufficient that the plant variety has not yet been sold or in other ways entered the market with the consent of the breeder. Article 10.1 (a) of the EC Regulation accepts a grace period of one year within the Community.

As we can see, the plant variety protection system is different from the patent protection system in two requirements: distinctiveness and novelty. For the examination of distinctiveness, plant varieties are compared with each other, and for the novelty examination, the marketing or sale, if any, of that variety prior to the application date is of interest. The novelty criterion

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<sup>51</sup> Hellstadius, p. 16.

<sup>52</sup> Hellstadius, p. 17.

in the patent system corresponds to the distinctiveness requirement of plant variety protection.<sup>53</sup>

#### **4.2.5 The scope of plant variety protection**

The plant breeder is the one granted the protection and the scope is comparable to the scope of patents. When protection is granted, the breeder's authorisation is necessary for anyone to commercially produce, reproduce, offer for sale, market, keep in stock, import and export.<sup>54</sup> If, for example, small farmers in developing countries stop using traditional seeds, which they are fully entitled to save from year to year and to further develop themselves, and switch to commercial seeds instead, plant breeder's rights may alter their entire situation.<sup>55</sup> Private or non-commercial use is not prohibited, nor experiments and breeding to develop other varieties.<sup>56</sup> Varieties which are essentially derived from the protected variety, or not clearly distinguishable from the protected variety fall within the scope of protection.<sup>57</sup> The reason for this increased scope of protection, added in the UPOV Convention in 1991, was that, earlier, protected varieties could be used for cross-breeding and creating new varieties, which were granted protection, without the original rights holder being compensated. The unequal effects grew as biotechnology gained ground, since it is possible to insert an alien gene into the DNA of a known plant variety and thereby creating a new variety. As a way of preventing the system from favouring biotechnological laboratory at the expense of traditional plant breeding, the exclusive right was extended.<sup>58</sup>

#### **4.2.6 Farmer's privilege**

For the purpose of safeguarding agricultural production, farmers are authorised to, under certain circumstances, use the seeds that they have obtained by planting propagation material of a variety sold by the rights holder.<sup>59</sup> This exception covers only a limited number of crops and agricultural plants, enumerated in Article 14.2 of the EC Regulation. The International Seed Treaty goes further and emphasises the great importance of farmers' rights to save, use, exchange and sell farm-saved seed or propagating material. Article 9 states that measures should be taken to protect and promote farmers' rights, including protection of traditional knowledge relevant to plant genetic resources, the right to equitably participate in sharing benefits and the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

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<sup>53</sup> Hellstadius, p. 19-20.

<sup>54</sup> Article 13 of the EC Regulation.

<sup>55</sup> De Vylder and others, p. 140-141.

<sup>56</sup> Article 15 of the EC Regulation.

<sup>57</sup> Article 14.5 (a) UPOV.

<sup>58</sup> Hellstadius, p. 21-22.

<sup>59</sup> SOU 2006:70, p. 96 and Article 14 of the EC Regulation.

## 4.3 Patentable invention or protectable plant variety – the grey zone

According to article 27.3 (b) of the TRIPS Agreement and Article 53 (b) EPC, plant (and animal) varieties are excluded from patentability, but not micro-organisms. As regards processes, essentially biological processes for the production of plants (and animals), may also be excluded. However, for micro-organisms as products and for non-biological or microbiological processes for producing plants (and animals), patentability must be available. The patentability will be determined by the interpretation of several terms. The first question relates to the product and consists in identifying a plant from a plant variety. The second question relates to the process, deciding if it is an essentially biological or non-biological and microbiological process, taken into consideration the definition of a micro-organism.

### 4.3.1 Defining the product

In 1985, the US led the way in extending the patent system more clearly to plants and plant material. By 1988 over 40 patents on crop plants had already been issued.<sup>60</sup> In 2001, the Supreme Court confirmed the legality of patents on plants. In Europe, we face a situation of legal uncertainties on this point. A ruling of the EPO Technical Board of Appeal in 1995 determined a claim for plant cells contained in a plant was unpatentable since it does not exclude plant varieties from its scope. Plant cells could not fall under neither the definition of plant, nor the definition of plant variety.<sup>61</sup> As a result, no plants were granted patents for several years. In 1999, the EPO Enlarged Board of Appeal decided on a more nuanced definition. Plant varieties containing genes introduced into an ancestral plant by recombinant gene technology are excluded from patentability. A claim wherein specific plant varieties are not individually claimed, is not excluded from patentability under Article 53 (b) EPC, even though it may embrace plant varieties.<sup>62</sup>

The concept of plant variety in Article 53 (b) EPC is equivalent to the definition used in PBR. Co-ordinating the definitions was a way of seeking uniformity in the systems. UPOV and the PBR system has experienced changes with the extension of the scope of protection, which has lead to the situation that gaps remain, and there is plant material that falls outside the scope of both systems. To determine if plant material is a plant variety and thereby excluded from patentability, an interpretation is often made of the prerequisites for patentability. This gives great importance to the patent

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<sup>60</sup> Dutfield, p.23.

<sup>61</sup> Case number G 0003/95 – EBA of 27 November 1995, <http://legal.european-patent-office.org/dg3/biblio/g950003ep1.htm> (retrieved 2007-01-11). See also Dutfield, p. 23.

<sup>62</sup> Decision G 1/98 of the Enlarged Board of Appeal dated 20 December 1999, [http://www.european-patent-office.org/dg3/g\\_dec/pdf/g980001.pdf](http://www.european-patent-office.org/dg3/g_dec/pdf/g980001.pdf) (retrieved 2007-01-11).



claims and the wording of the patent application.<sup>63</sup> The gene sequence must be isolated from its natural environment, its functions must be determined and documented and a technical application stated. Article 3 (2) of the Biotech Directive<sup>64</sup> states that the biological material is patentable even if it previously has occurred in nature. A GM plant can be subject to an invention, on condition that the invention creating that plant is not limited technically to one single plant variety. How that plant variety was produced is of no importance in this aspect. The mere fact that a plant variety is created through biotechnology does not automatically imply patent protection. If the gene sequence, for instance making an organism pest resistant, is inserted into the DNA of plant, the patent will also include that GM plant.<sup>65</sup> GM plants can generally reproduce or multiply in an identical or differentiated form. The patent covering the original GM plant will cover its identical offspring as well, if the characteristics of the reproduced organisms originate from the parent organism's patented gene sequence.<sup>66</sup>

### 4.3.2 Defining the process

The second question related to the patentability of plants consists of deciding if the process is essentially biological or if it is non-biological and microbiological. First, we have to look at the definition of a micro-organism. A clear definition does not exist, neither in European, US, nor Japanese patent law, although the granting offices have interpreted the term as to include plant or animal cells. This is a broad interpretation, since it implies that a single cell in a multi-cellular organism is itself an organism, and other countries are not necessarily demanded to adopt the same view.<sup>67</sup>

An “essentially” biological process is a broader term compared to the previously used “purely” biological, changed to include such biological processes where technical devices were utilised to carry out the breeding process.<sup>68</sup> EPO guidelines on the subject clarifies that the definition of the non-patentable, essentially biological process is dependent on the amount of technical intervention by man. If the intervention plays a significant role in determining the result it is desired to achieve, the process would not be excluded from patentability.<sup>69</sup> The EPO Technical Board of Appeal further declared, in 1995, that this technical intervention could consist of at least one technical step, which cannot be carried out without human intervention and which has a decisive effect on the end result. In contrast, conventional plant and animal breeding methods and other techniques such as artificial insemination would not be patentable.<sup>70</sup> Article 2.2 of the Biotech Directive offers a slightly stricter view by stating that a process of production is

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<sup>63</sup> Hellstadius, p. 69.

<sup>64</sup> Directive 98/44/EC of 1998 on the legal protection of biological inventions.

<sup>65</sup> SOU 2006:70, p. 94.

<sup>66</sup> SOU 2006:70, p. 94-95.

<sup>67</sup> Dutfield, p. 29.

<sup>68</sup> Dutfield, p. 29.

<sup>69</sup> Dutfield, p. 29.

<sup>70</sup> Case number G 0003/95 – EBA of 27 November 1995. See also Dutfield, p. 30.

essentially biological if it consists entirely of natural phenomena such as crossing or selection, although there is not a large difference in significance, since the EPO has accepted this definition.<sup>71</sup>

### 4.3.3 Final remarks

For patentability of biological material in general, a restrictive approach is appropriate. It has been suggested that the exclusion from patentability of plant varieties, likewise should be interpreted narrowly, to the extent where an uncertainty remains in drawing up the dividing line between patentable plants and non-patentable varieties.<sup>72</sup>

Since the two systems have different protection purposes and are overlapping to some extent, the situation may occur that two rights holders are infringing each other's protected property and are restrained from commercial use. This situation is remedied in Article 12 of the Biotech Directive, by cross-licences authorising the two rights holders to use what the other has been granted an exclusive right for, without being charged guilty of infringement.<sup>73</sup> The fact that the Biotech Directive regulates this possibility of cross-licensing may indicate that the drafters viewed the prospect of double protection favourably. The removal of the ban of double protection from the 1991 UPOV, indicates the same, although the ban remains in the EC Regulation.<sup>74</sup>

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<sup>71</sup> Dutfield, p. 24.

<sup>72</sup> Westerlund, *Biotech Patents – Equivalency and Exclusions under European and U.S. Patent Law*, 2001, p. 352.

<sup>73</sup> SOU 2006:70, p. 97.

<sup>74</sup> Westerlund, p. 452.

# 5 Compulsory licensing of GM food

Agenda 21, the United Nations program related to sustainable development, adopted at the Rio Conference 1992, acknowledged the unequal situation with advanced technologies in the developed countries and the non-access to this development in the developing countries. Paragraph 34.18 of Agenda 21, contains different ways of facilitating the access and use of environmentally sound technologies especially in the developing world. Concerning privately owned technologies, one of these ways is to prevent the abuse of IPRs, including adopting rules with respect to the acquisition through compulsory licensing, (with the provision of equitable and adequate compensation).<sup>75</sup>

This chapter is the core of my thesis. So far, I have examined the patent system concerning biotechnology patents and the equivalent protection system for plant varieties that are excluded from patentability. In this chapter, I will examine the possibility for the technical progress made in the developed world to reach the developing world, allowing them to take part through compulsory licensing.

## 5.1 Balancing the patent system

A compulsory licence is an authorisation granted by the relevant national body to use a patent and produce copies of the patent protected product without the consent of the patent owner. Compulsory licences are explicitly allowed by the TRIPS Agreement, under certain conditions. Access to a patented material for research and breeding, if not otherwise ensured, may be obtained by compulsory licences, if provided for by national legislation. The licences may be granted on grounds related to public interest, lack of exploitation of the invention, anti-competitive practices by the patent holder, emergency, conservation or protection of the environment, or other reasons.<sup>76</sup> Conventional licences are quite common, on basis of a licence agreement on commercial terms, frequent in the software and the pharmaceutical industry.

Relating to GM food, the compulsory licence system must be studied from two different aspects, since there are two types of legal protection for the products and processes relating to GM food, as we have seen in chapters 3 and 4. Generally, when talking about compulsory licensing, it is as a counterbalance to the patent system. More seldom do we hear about compulsory licensing as a counterbalance to the PBR system. The reason for

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<sup>75</sup> Paragraph 34.18 (e) iv of Agenda 21.

<sup>76</sup> Correa, *Access to Plant Genetic Resources and Intellectual Property Rights*, Background Study Paper no. 8, April 1999, p. 18.

this might be that the patent system has been used to a larger extent than the PBR system, because of its wider range of application. Another reason is that the gene modification techniques calling for a new type of PBR system have developed over the past decades and the protected plant varieties are not of the same economic importance as the most of the inventions justifying the patent system. My focus will therefore be on the compulsory licensing in relation to patents, even though I give examples of the equivalent procedure that should be applicable in the case of plant varieties.

## 5.2 The legal framework

The TRIPS Agreement attempts to strike a balance between the long-term social objective of providing incentives for future inventions and creation, and the short-term objective of allowing people to use existing inventions and creations.

### 5.2.1 The TRIPS Agreement

The objective of the TRIPS Agreement, as stated in Article 7, is the protection and enforcement of IPRs, promoting technological innovation and transfer and dissemination of technology, to a mutual advantage of producers and users of technological knowledge, aiming for social and economic welfare.

The TRIPS Agreement provides flexibility for governments to fine tune the protection granted in order to meet the social goals. TRIPS allows compulsory licensing as a way of specifically seeking a balance between promoting access to existing *drugs* and promoting research and development into new drugs. But the term “compulsory licensing” does not appear in the agreement. Instead, the phrase “other use without authorization of the right holder” appears in the title of Article 31. Compulsory licensing is only part of this since “other use” includes use by governments for their own purposes.<sup>77</sup>

The person or company applying for a licence must first have attempted to establish a voluntary licence agreement with the rights holder on reasonable commercial terms, but failed.<sup>78</sup> If a compulsory licence agreement is issued, adequate remuneration must still be paid to the patent holder.<sup>79</sup> There are exceptions to the need of seeking a voluntary licence agreement, in the presence of national emergency, other circumstances of extreme urgency or public non-commercial use or governmental use or anti-competitive practices, according to Article 31 (b). Some additional requirements must be met, in particular, the licensee cannot be given exclusivity to produce, and

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<sup>77</sup> *TRIPS and Pharmaceutical Patents*, WTO OMC Fact Sheet, September 2006, p. 4. See also Article 8 of the TRIPS Agreement.

<sup>78</sup> Article 31 (b) of the TRIPS Agreement.

<sup>79</sup> Article 31 (h) of the TRIPS Agreement.

the grant of a compulsory licence is mainly for the supply of the domestic market.<sup>80</sup>

What Article 31 of the TRIPS Agreement grants with the compulsory licence is access to what is patent protected. The granted country must by own means produce the product, Article 31 (f) states that “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”, excluding export as an option. Here we face a practical problem of capacity. This capacity problem affects the least developed countries the most, countries that are in greatest need of access to advanced technology that could improve the health situation.

## 5.2.2 The DOHA Declaration

The 2001 Doha Ministerial Conference decided that the provision in Article 31 (f) of the TRIPS Agreement, that compulsory licences must be granted mainly to supply the domestic market, should be changed, so that countries unable to manufacture the pharmaceuticals could obtain cheaper copies elsewhere if necessary. This resulted in the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

The Doha Declaration allows generic copies made under compulsory licences to be exported to countries that lack production capacity, provided certain conditions and procedures are followed. All WTO member countries are eligible for import under this decision, but 33 developed countries have announced that they will not use the system to import.<sup>81</sup> They have done this to guarantee that the decision favours the countries that need it the most. Eleven more said they would only use the system to import in national emergencies or other circumstances of extreme urgency. Several potential exporting countries have changed their laws and regulations in order to implement the waivers and to allow production exclusively for export under a compulsory licence.<sup>82</sup>

The Doha Declaration also clarifies that each member is free to determine the grounds upon which the licences are to be granted. This is a useful corrective of the previous idea that some form of emergency is a pre-condition for compulsory licensing. The reference made to national emergencies and extreme urgencies in the TRIPS Agreement is only to indicate that under these circumstances there is no need to try to obtain a voluntary licence before resorting to compulsory licensing. Each member country has the right to determine what constitutes a national emergency or other circumstance of extreme urgency, and the Declaration states that

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<sup>80</sup> TRIPS and Pharmaceutical Patents, WTO OMC Fact Sheet, September 2006, p. 4.

<sup>81</sup> *Compulsory Licensing of Pharmaceuticals and TRIPS*, TRIPS and Health: Frequently Asked Questions, [http://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm) (retrieved on 2007-01-09).

<sup>82</sup> TRIPS and Pharmaceutical Patents, WTO OMC Fact Sheet, September 2006, p. 6. The countries that have made the necessary changes (as of September 2006) are the EU, Norway, India and Canada.

public health crises can fit the bill, naming HIV/AIDS, tuberculosis and malaria as examples of epidemics.<sup>83</sup>

The changes were put into practice in 2003 and in 2005, members agreed to make this decision a permanent amendment to the TRIPS Agreement, which will take effect when two thirds of members accept it and for the following members, the changes will take effect as soon as they accept the amendment.<sup>84</sup> So far, only three countries have accepted the amendment, The United States, Switzerland and El Salvador.<sup>85</sup> If, or when, the amendment has been accepted, an Article 31 a will be added to TRIPS, prescribing the export possibility. The time limit expires 1 December 2007. The provisional amendment from 2003 is applicable until the new TRIPS Agreement enters into force. However, for the changes to enter into effect, each member country must make the necessary changes in national legislation for implementation.<sup>86</sup> In May 2006, to comply with the Doha Declaration, the European Union adopted Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

Some argue that the Declaration does not change the existing rules in TRIPS.<sup>87</sup> Article 8.1 TRIPS states that the WTO members may adopt measures to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that these measures are consistent with the provisions of TRIPS. Rather, the Doha Declaration, together with Article 8 of TRIPS, intends to influence the interpretation of TRIPS, where there is any doubt of the meaning of its provisions. Interpretations of terms such as “reasonable period” of time for negotiation and “adequate compensation” (in Article 31 TRIPS), should consequently be affected by public health considerations.<sup>88</sup> Moreover, TRIPS and the Doha Declaration fulfil an essential political function, supporting the use of existing flexibilities in the face of political pressure.<sup>89</sup>

### **5.2.3 Compulsory licensing of GM crops under patent law and PBR**

There is a grey area between the patent system and the PBR system, resulting in double protection and infringing property rights. As I have mentioned, the solution to this problem, where two rights holders, granted

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<sup>83</sup> Article 5 of the Doha Declaration; see also TRIPS and Health: The Doha Declaration explained, [http://www.wto.org/english/tratop\\_e/trips\\_e/healthdeclexpln\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/healthdeclexpln_e.htm) (retrieved 2007-01-09).

<sup>84</sup> TRIPS and Pharmaceutical Patents, WTO OMC Fact Sheet, September 2006, p. 1.

<sup>85</sup> *Countries accepting amendment of the TRIPS Agreement*, [http://www.wto.org/english/tratop\\_e/trips\\_e/amendment\\_e.htm](http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm) (retrieved 2007-01-09).

<sup>86</sup> Article 1.1 of the TRIPS Agreement.

<sup>87</sup> Caulfield and von Tigerstrom, *Gene Patents, Health Care Policy and Licensing Schemes*, TRENDS in Biotechnology Vol 24 No. 6 June 2006.

<sup>88</sup> Caulfield and von Tigerstrom, 2006.

<sup>89</sup> Caulfield and von Tigerstrom, 2006.

exclusivity, infringe the other right under patent law or under PBR, there is a possibility in Article 12 of the Biotech Directive of cross- and compulsory licensing. I will now examine the substance of compulsory licensing under patent law and PBR.

A prerequisite set fourth in Article 12 of the Biotech Directive, as well as in the recitals 52 and 53, the invention or plant variety for which the compulsory cross-licence is needed, has to constitute a significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety. Another prerequisite is that the applicant for the licence has unsuccessfully tried to obtain a contractual licence from the right holder. These are the only conditions specifically expressed in the Biotech Directive, but for the actual grant of compulsory licence, Article 31 of the TRIPS Agreement and provisions under national law must be taken into consideration.<sup>90</sup> The owner of the first patent shall in turn be entitled to a cross-licence to use the invention of the second patent, as stipulated in Article 31 of the TRIPS Agreement.

An EC plant variety right may also be subject to a compulsory exploitation right. This is regulated in Article 29 of the EC Regulation. Compulsory licences for a Community plant variety may only be granted by the Community Plant Variety Office, and not by a Member State.<sup>91</sup> This corresponds to Article 17 of the UPOV. In contrast to the provisions in the Biotech Directive, a plant variety may be subject to compulsory licensing under the EC Regulation only on grounds of public interest. The public interest requirement may include the need to supply the market with material offering specified features, or to maintain the incentive for continued breeding or improved varieties. This means that it would be difficult to obtain a compulsory licence if the PBR holder already supplies the market with sufficient variety material.<sup>92</sup> It does not seem that the legislators have considered the situation, more than in passing, of compulsory licensing of GM crops for the benefit of farmers in the developing world. This might be because there are no developing countries within the EU, and not the same sort of lobby groups as in the NGOs dealing with the issue. Compulsory licences seem to be a complex issue in practice. On one hand, a restricted use has been suggested in doctrine, since the availability of such licences could risk the diminishing the concept of the exclusive right. On the other hand, the grant of compulsory licences is limited in practice, since the conditions of grant are to be compared with force majeure.<sup>93</sup>

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<sup>90</sup> Westerlund, p. 453.

<sup>91</sup> See paragraph 7 of Article 29 of the Regulation.

<sup>92</sup> Westerlund, p. 454.

<sup>93</sup> Westerlund, p. 454-455.

## 5.3 Fighting HIV and AIDS – compulsory licensing in practice

Around 40 million people were living with HIV in 2006, whereof two thirds live in sub-Saharan Africa. Provisions of antiretroviral therapy has expanded dramatically in this area, where more than one million people were receiving antiretroviral treatment by June 2006, a tenfold increase since December 2003. Yet, the HIV epidemics continues to grow in several countries.<sup>94</sup> The AIDS crisis has forced the international community to collaborate and the challenge has been to find a balance between the need to protect the large investments in developing new medicines and the goal of providing the essential drugs to poor countries.<sup>95</sup> The compulsory licensing system has opened the door, at least in theory, for the developing countries to access to the otherwise extremely expensive treatment. However, few compulsory licences have been issued to this date.<sup>96</sup> It is too early to draw any conclusions from the amendments of the TRIPS. It has been argued that it is not the lack of production that presents the true obstacle. Most essential medicines are not protected by patents in developing countries, often poverty, corruption and lack of health-care infrastructure are equally important reasons that access cannot be secured.<sup>97</sup>

It has been suggested that countries, in their legislation, should provide powers to use compulsory licensing, in accordance with the TRIPS Agreement, where these powers might be useful as one of the means available to promote, inter alia, research that is directly relevant to the specific health problems of developing countries.<sup>98</sup>

It is interesting to see if we have anything to learn from the pharmaceutical industry, with AIDS medicines as a focal point, when predicting the prospects of compulsory licensing of GM food. It would seem that access to antiretroviral treatments in the developing world is at the extreme end of what we can expect for the GM food industry in the future.

The question of compulsory licences of antiretroviral medicines in Brazil has caused debate all over the world and may serve as an illustrative example. No compulsory licences have ever been issued by the government, but the initial steps of the process have been taken, at several occasions, as a part of the negotiations of purchase from foreign pharmaceutical companies. If the price is too high, the Brazilian Health Department has threatened to grant a compulsory licence for local production, making the companies

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<sup>94</sup> UNAIDS/WHO *AIDS Epidemic Update*, December 2006, p. 1, 6 and 10.

[http://www.unaids.org/en/HIV\\_data/epi2006/default.asp](http://www.unaids.org/en/HIV_data/epi2006/default.asp) (retrieved on 2007-02-08).

<sup>95</sup> Lidgard and Atik, *Facilitating Compulsory Licensing Under TRIPS in Response to the AIDS Crisis in Developing Countries*, 2005, p. 2.

<sup>96</sup> *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WHO, 2006, p. 117.

<sup>97</sup> Lidgard and Atik, p. 16.

<sup>98</sup> *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WHO, 2006, p. 55.



lower the price. The latest agreement was signed with the pharmaceutical company Gilead, in May 2006, wherein the price for the antiretroviral medicines were half of the price in previous agreements.<sup>99</sup> This shows that the institution of compulsory licensing may serve as good tactics in the negotiations. In 2005, the public opinion in Brazil called for the immediate granting of compulsory licences for antiretroviral medicines. The Health Department stated that the conditions were not met for the grant to be made. The relatively low levels of HIV in Brazil (around 600 000 are infected with the virus) had made HIV possible to control, wherefore the situation was not a national emergency. At the same time, it was highly unlikely for a grant to be made on the grounds of public interest. The Health Department reasoned that a voluntary agreement could provide important advantages and that they for local production based on a compulsory licence, at least for a transitional period, would be forced to buy copies from foreign producers, and the best offer for those copies had been less beneficial than a voluntary agreement.<sup>100</sup> The statement made in Brazil gives us certain implications of future developments. By avoiding local production, they are discarding the opportunity to develop the necessary knowledge in the field of production of those medicines. Relying on imports of compulsory licensed drugs or GM crops, for that matter, the country will lack the incentives to promote technological growth of its own.<sup>101</sup> They are also dependent of foreign companies that are governed by commercial and economic interests, which is a dangerous path to follow in the long run. Compulsory licensing was avoided because it was not worth it, economically, and probably, because it had never been done before.

## 5.4 Key issues concerning compulsory licences of GM food

The development of the biotechnology field is causing a race to the patent offices as an increasing number of GM products is created. As a reaction to this situation, voices have been raised that good licensing practices might be a way of balancing the system.<sup>102</sup> An example of this is the OECD Guidelines for the Licensing of Genetic Inventions, published in 2006, directed to the 30 members of the organisation, all developed countries.<sup>103</sup>

As we have seen, it is unclear to what extent the international regulations apply to permit compulsory licensing in the GM sector. In most cases the

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<sup>99</sup> Carl Josefsson, *Patent – verktyg för global konkurrenskraft eller hot mot nationella intressen? Motsättningarna i brasiliansk patentpolitik*, Memo from the Swedish Embassy in Brazil, 2006, p. 31-32.

<sup>100</sup> Josefsson, p. 33.

<sup>101</sup> Fayerman, *The Spirite of TRIPS and the Importation of Medicines Made under Compulsory License after the August 2003 TRIPS Council Agreement*, Northwestern Journal of International Law & Business, Fall 2004:25, p. 271.

<sup>102</sup> Caulfield and von Tigerstrom, 2006.

<sup>103</sup> The guidelines can be found on the OECD website, [www.oecd.org](http://www.oecd.org).

legal texts explicitly refer to *pharmaceuticals* and nothing else.<sup>104</sup> In addition, there is still limited evidence regarding the potential adverse effect of patents on access to genetic technologies and even the research environment.<sup>105</sup> I will present a couple of arguments questioning the applicability of compulsory licensing in the GM sector.

### 5.4.1 Case-by-case granting

The TRIPS Agreement sets the minimum standards for the intellectual property protection, yet the existing conditions might limit the usefulness of compulsory licensing as a policy option for the genetic technologies.<sup>106</sup> The requirement of case-by-case and limited granting<sup>107</sup> calls for an extensive investigation for each application, with a resolution on the gravity of the situation, defining whether an emergency or urgency is immediate. There would never be a routine for the procedures and the examination by the public authorities would most certainly be lengthy.

### 5.4.2 Transaction costs

Compulsory licences may be granted after reasonable efforts to negotiate a voluntary agreement on commercial terms, according to TRIPS.<sup>108</sup> This means that the farmer, or the agricultural company in the developing country must first search the market of suppliers and patent holders of the desired GM crop for possible contracting parties, then pursue negotiations, and at some realise that a consensus is beyond reach and turn to the public authorities. However, it is unclear *how many* different (failed) negotiations and how many different considered suppliers that lie in the concept of “reasonable effort”. What is the time perspective? If time is of the essence, in the situation of national emergency or other circumstances of extreme urgency (terms defined at a national level), the applicant is relieved from pursuing these negotiations. But if the situation is not classified as a national emergency, for how long must the applicant seek a voluntary agreement? Clearly, the numerous negotiations cause delays and uncertain interruption in the work. Presumably, new suppliers enter the market every year and the trends in prices and selection of available goods change all the time. The applicant must possess excellent negotiation skills, while at the same time, doubtlessly be the weaker party, in need, so to say. In addition, the government has the final word and the case-by-case investigation makes the outcome impossible to foresee, thus, quite an unattractive alternative.

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<sup>104</sup> For instance, the Regulation (EC) No 816/2006 on Compulsory Licensing of Patents Relating to the Manufacture of Pharmaceutical Products for Export to Countries with Health Problems.

<sup>105</sup> Caulfield and von Tigerstrom, 2006.

<sup>106</sup> Caulfield and von Tigerstrom, 2006.

<sup>107</sup> Article 31 (c) TRIPS.

<sup>108</sup> Article 31 (b) TRIPS.

### 5.4.3 Adequate compensation

A compulsory licence is not free. Article 31 (h) TRIPS proscribe adequate compensation, meaning that the cost of a compulsory licence might be less than the cost of a commercial licence but could still be significant.<sup>109</sup> The licence fees might amount to market value. It has been suggested that compulsory licensing, as a result, could be used as a measure of restraining price increase.<sup>110</sup> Clearly, this was not the objective from the beginning, and it distorts the higher cause of the very existence of the compulsory licensing system. Nevertheless, if the system, as a whole, was functioning well, the consequence of price control would be a welcome side effect.

### 5.4.4 Delayed relief

The interesting terms to examine are “emergency” and “urgency”. The scenario associated with these expressions often include some sort of effects on humans and leading to human suffering, superior to what the market or the state is capable of managing. The situation could occur as a result of the outbreak or uncontrollable spreading of a disease. This is probably the common perception of an emergency or urgency. Hunger and starvation are acute problems, but the process of compulsory licensing of patented GM crops would not be a relief fast enough. Suppose for a moment that a compulsory licence would be granted for a GM crop. The farmer would then first have to sow the field and wait for the harvest until the GM crop comes in use for its lifesaving purpose. Nevertheless, lack of food most certainly entails many severe health conditions and is often a contributory cause for diseases that in the end motivates compulsory licensing of drugs. Being able to prevent that condition could be a reason to consider compulsory licensing of GM crop. Another reason is that the wording in the TRIPS Agreement, although focussing on pharmaceuticals, never explicitly excludes other types of products, such as GM crops.

The weak point in the argument may be that “urgency” indicates a severe situation in presence and calls for immediate action, with immediate relief, and “emergency” indicates the unforeseeable appearance of the situation, but with the same need of immediate relief, and compulsory licensing of GM food products may fail to meet this need. However, the same emergency, for example a natural catastrophe, could result in both epidemics and in starvation. With epidemics, different people are inevitably in different stages of the disease, when a hypothetical body finally takes action, seeking a cure through compulsory licensing.

The delayed effect of compulsory licensing of a GM crop might be more considerable than with a drug, but not for certain. In both cases, there is a production time to take in consideration.

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<sup>109</sup> Caulfield and von Tigerstrom, 2006.

<sup>110</sup> Caulfield and von Tigerstrom, 2006.

### **5.4.5 Differences in between GM food and pharmaceuticals**

Plant genetic resources for food and agriculture are placing the developing countries in a fairly weak position, for several reasons. First, they lack the scientific and technological capacity to capture the benefits from agrobiodiversity themselves.<sup>111</sup> Second, no country is self-sufficient, not even the biodiversity rich, tropical developing countries. For these reasons, the developing countries are dependent on imports from developed countries. Concerning pharmaceuticals, on the other hand, the transfer of biogenetic resources are more likely to flow in a general South to North direction.

Another essential difference is that with the life-saving pharmaceuticals, the developed countries have practically no other choice than either accessing to the medicines, or not having any medicines at all. The situation is different with GM food. Here, there is a choice. We may choose either GM food or non-GM food. Considering this situation, we have to justify the choice of GM food. This justification can be made if GM food benefits the developing country more important than those of non-GM food. I doubt that this will be the case.

### **5.4.6 TRIPS-plus**

The United States has been one of the WTO members pushing for a TRIPS-plus position. The US has entered a number of bilateral and regional trade agreements that contain provisions which impose stricter IPR standards than TRIPS, in order to reduce the negative impact of the WTO developments.<sup>112</sup> Trade agreements concluded by the US with countries such as Australia, Jordan, Singapore and Morocco involve significant restrictions on compulsory licensing. For example, the Australia-United States Free Trade Agreement permits compulsory licensing only in cases of anti-competitive behaviour, public non-commercial use, in a national emergency or other circumstances of extreme urgency. Such provisions substantially constrain policy options for parties to these agreements.<sup>113</sup>

## **5.5 Alternatives to compulsory licences**

Manifestly, compulsory licensing for the production of GM food products is hardly feasible under the conditions and the international policies of today. The key issues that I examined in the previous sub-chapter, related to technicalities. Now, I shall present a couple of methods, either to circumvent the conditions set forth in TRIPS, or as alternatives to the compulsory licensing system, as a whole. In this chapter, we are still only concerned with the mere technical solutions, although many non-technical elements often have to be taken into consideration.

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<sup>111</sup> Dutfield, p. 6.

<sup>112</sup> Lidgard and Atik, 2005, p. 15.

<sup>113</sup> Caulfield and von Tigerstrom, 2006.

### 5.5.1 Parallel imports and exhaustion of rights

The TRIPS Agreement does not restrict the right to parallel imports. A country can import a patented GM crop against the wish of the patent holder, from a third country where it is cheaper. For example, AIDS drugs are cheaper in India and Brazil than in many other countries, which is why other developing countries, in particular, have strong reasons for wanting to import medicines from such countries.<sup>114</sup> In principle, it should be possible to use the TRIPS Agreement to defend the right to parallel imports. Once a company has sold a batch of its products, its patent rights are exhausted on that batch and it no longer has any rights over what happens to that batch. Article 6 TRIPS gives that only its provisions dealing with non-discrimination (involving “national treatment” and “most-favoured-nation treatment”), can be used to address the issue of exhaustion of IPRs in a WTO dispute. Even if a country allows parallel imports in a way that another country might think violates the TRIPS Agreement, this cannot be raised as a dispute in the WTO unless fundamental principles of non-discrimination are involved.<sup>115</sup> In 5 (d) of the Doha Declaration a clarification explains that members can choose how to deal with exhaustion in a way that best fits their domestic policy objectives. However, parallel imports have proved to be difficult to accomplish in practice. The US, for example, implemented economic sanctions against South Africa when the latter planned to introduce limited rights to compulsory licensing and parallel imports of certain AIDS drugs. The sanctions were finally lifted after an extensive campaign in the US, but later, a group of pharmaceutical companies sued the South African state. They claimed that the new regulations were in breach of both the South African constitution and the TRIPS Agreement. The dispute was finally settled between the companies and the South African Government.<sup>116</sup>

One way of motivating the existence of the exhaustion principle for the developed countries, is to find a compromise and promote bilateral and multilateral trade agreements to avoid counterfeit trade and trade diversion of products intended for developing countries. By excluding developing countries from these agreements, price differentiation could be secured between the developed and the developing world.<sup>117</sup>

### 5.5.2 Non-profit academic research institutions

The interest of technology transfer and commercial application would mostly be served by the widest possible dissemination of knowledge through publication.<sup>118</sup> The US lack an effective research exemption, similar to the one mentioned earlier. They have discussed other ways to

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<sup>114</sup> De Vylder and others, p. 142.

<sup>115</sup> *TRIPS and Pharmaceutical Patents*, WTO OMC Fact Sheet, September 2006, p. 5.

<sup>116</sup> De Vylder and others, p. 142.

<sup>117</sup> Lidgard and Atik, p. 4.

<sup>118</sup> *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WHO, 2006, p. 56.

facilitate further research for the public good. There are a number of examples where universities have licensed technologies on favourable terms to non-profit enterprises. Yale, for example, has given a licence to the non-profit pharmaceutical company One World Health, to develop novel azoles for the treatment of Chagas disease. The same enterprise was provided a co-exclusive, royalty free licence to develop a new technology for the production of one type of malaria treatment.<sup>119</sup>

### 5.5.3 Voluntary Donation Schemes

If the goal is to secure access to GM food from developed countries to developing countries, voluntary donation schemes is an alternative. Donations could be made both of seeds to be planted, or of the final product. The idea consists of companies in wealthier countries being encouraged to voluntarily donate surplus supplies to poorer countries. The company would benefit from it by favourable publicity, which could lead to increased shareholder investments and sales, and thereby influence other companies to do the same. The government could encourage the companies to undertake donation plans by providing tax incentives for companies willing to participate.<sup>120</sup> There are some obvious risks. The surplus supplies would seldom remain constant, and would not be of recurrent nature, since the profit-driven company in the case of frequent surplus in production would make necessary adjustments to avoid this. Furthermore, donations made on occasions of national emergency would not harmonise with the purpose of TRIPS, to promote technology transfer to the developing world.<sup>121</sup> If a surplus is to be donated, it would also be more appropriate, and certainly less controversial to donate non-GM seeds and crops.

### 5.5.4 Pool of collective resources

When technology is in the hands of a private company, the company often has economical interests in that property. It might be a good idea to transfer the technology into the public domain, making it the property of a public authority, if the society has an interest in having that technological knowledge publicly available, for reasons of public health.<sup>122</sup> These “pools” can either be organised at a national level, or by cooperation between a number of developing countries, in need of either the knowledge or actual seed. This is actually something that is done, but not with the collection and distribution of GM seeds, but of non-GM seeds. An example of this type of sharing institutions is the Consultative Group on International Agricultural Research (CGIAR), sponsored by the FAO, the International Fund for Agricultural Development, The United Nations Development Program (UNDP) and the World Bank. The membership consists of 46 countries (whereof half are developing countries), four private foundations and 13

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<sup>119</sup> *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WHO, 2006, p. 58.

<sup>120</sup> Fayerman, p. 272.

<sup>121</sup> Fayerman, p. 273.

<sup>122</sup> Thumm, p. 1411.

regional and international organisations. The CGIAR supports an international network of 16 agricultural research centres, which together hold the largest ex situ collections of plant genetic resources, with over 700.000 crop, forage and agro-forestry species, encompassing farmers' varieties, improved varieties and wild life species. These are treated as public goods and as such are made freely available to researchers anywhere in the world subject to a standard material transfer agreement on the understanding that no intellectual property protection may be sought on the material received.<sup>123</sup>

The collectiveness is itself an advantage for the farmers. With a national or regional organisation, the individual farmer would not need to negotiate alone with suppliers, making this a better alternative than the non-existence of a cooperative of some sort.<sup>124</sup>

### 5.5.5 Open source genomics

Over the past couple of years, IPR sceptics and others have seen and taken impression of a new type of technology sharing, the open source technology. In the software industry, the source code of the computer software available under a copyright licence that permits users to study, change, and improve the software, and to redistribute it in modified or unmodified form.<sup>125</sup> Starting with software, it has now expanded in other fields, such as biotechnology. Plant breeders have started to consider open source genomics, envisioning the sharing of genes.<sup>126</sup> In Australia, a not-for-profit plant biotechnology research centre called CAMBIA was founded in 1992, providing their technology using an open source model. As a way of working around the current IPR system, they, amongst other, offer royalty-free patented technologies in exchange for reciprocal sharing agreements.<sup>127</sup> In the concept of open science, lie three things: full and timely publication of results, absence of intellectual property restrictions, and increased pre- and post-publication transparency of data and activities within research groups.<sup>128</sup> An important part of the technology sharing is databases, rather than physical compounds. Clearly, the research community of the developed world is not ready to accept and adopt this new system, and it is unclear if this system will be accepted in the near future. In literature, it has been suggested that an "acceptable" agreement must accelerate science.<sup>129</sup> I believe that there will probably not be a change in attitude before those agreements also are mutually beneficial.

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<sup>123</sup> Dutfield, p. 8.

<sup>124</sup> Fayerman, p. 273.

<sup>125</sup> [www.wikipedia.org](http://www.wikipedia.org) search of "open-source software". (retrieved on 2007-01-10).

<sup>126</sup> Rifkin, *Beyond Genetically Modified Crops*, Washington Post, July 4 2006.

<sup>127</sup> [www.cambia.org](http://www.cambia.org) (2007-01-10)

<sup>128</sup> Maurer, *New Institutions for Doing Science: From Databases to Open Source Biology*, 2003, p. 4. [http://www.merit.unimaas.nl/epip/papers/maurer\\_paper.pdf](http://www.merit.unimaas.nl/epip/papers/maurer_paper.pdf) (retrieved on 2007-01-10).

<sup>129</sup> Maurer, p. 10.

The concrete problem of open source genomics, in respect to GM agriculture in the developing world, is that the need of a working infrastructure of research and development remains. Open source biotechnology, or licensed technology, for that matter, requires a certain level of manufacturing activity, to process the information into, for example, a GM crop, ready for cultivation. Still, open source *technology*, may, and should, play an important role in the future, when the domestic agricultural infrastructure has developed, can profit from and take part in, the technology sharing.

### **5.5.6 New technologies in the future**

Jeremy Rifkin, author and founder of the Foundation on Economic Trends, wrote an article in July 2006 describing a new agricultural technology called marker-assisted selection or MAS.<sup>130</sup> This method allows scientists to identify genes associated with different wanted traits, and then scan crop relatives for the presence of those genes. By locating desired traits in other varieties of a particular food crop, or its relatives growing in the wild, the scientists can crossbreed the plants to improve the crop, without using molecular splicing techniques to transfer the gene from an unrelated species. Breeding of a new variety within a species reduces the risk of environmental harm and potential adverse effects associated with GM crops. MAS might, according to Rifkin, eventually replace genetically modified food, as we know it today, being easier, cheaper and one step closer to sustainable farming, although much research is still to be done. I will put the new MAS technology aside for now for someone else to study its development in a few years time.

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<sup>130</sup> Rifkin, 2006.



## 6 Controversial third world aid

Having examined the technical and legal framework of compulsory licensing of GM food, I intend, in this chapter, to examine the appropriateness of the system considering additional social issues. The resistance is twofold, practical and ethical.

### 6.1 Facts and fiction

According to the United Nations “Millennium Goals Report 2006”, an estimated 824 million people in the developing world were, in 2003, affected by chronic hunger (the state of lacking the food needed to meet the daily needs). The worst-affected regions are sub-Saharan Africa and Southern Asia. The number of hungry people in Eastern Asia declined in the early 1990s, but is once again on the rise.<sup>131</sup> At the same time, half of the developing country populations are still lacking basic sanitation, including access to safe water.<sup>132</sup>

According to the FAO report “The State of Food Insecurity in the World 2006”, hunger reduction is necessary for accelerating development and poverty reduction. Hunger is, at the same time, a consequence and a cause of poverty. Hunger negatively affects health, labour productivity and investment choices, perpetuating poverty. Agricultural growth is critical for hunger reduction and the majority of the poor live in rural areas. The FAO has come to the conclusion that technology can contribute, but under the right conditions, adapted to local conditions that favour small-scale farmers, increases farm income and lower food prices. Trade may contribute to hunger reduction and poverty alleviation, but market infrastructure, institutions and domestic policy reforms and safety nets are required to ensure the benefits. Public investments in, for example in agricultural research and education, are essential for agricultural growth. Another observation that the FAO has made is that development assistance does not target the neediest countries and tends not to target sufficiently the countries with low levels of undernourishment.<sup>133</sup>

We are currently producing food surpluses, which means that the world hunger problem is rather a distribution problem than a production problem.<sup>134</sup> But is it not a production problem? The FAO underlines the importance of local production and areas of hungry and poor people lack, de facto, a sufficient level of local production.

The difficulty of evaluating claims and counter-claims concerning GM crops and food, has allowed facts and propaganda to circulate freely,

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<sup>131</sup> UN *Millennium Goals Report 2006*, p. 5.

<sup>132</sup> UN *Millennium Goals Report 2006*, p. 16.

<sup>133</sup> FAO, *The State of Food Insecurity in the World*, 2006, p. 28-29.

<sup>134</sup> Toke, p. 8.

agitating enthusiasts on both sides. It is very difficult to draw a line between science and politics on this issue, perhaps as a result of the lack of proof and the lack of a purely black-and-white picture. The scientists are getting involved in politics because they are the ones consulted for information and interpretation of the scientific matters that are unknown to politicians and the public.<sup>135</sup> The politicians are getting involved in science because there are many other values involved in the issue of GM food. The politics of biotechnology are influenced by social, economic, environmental and health factors. For those same reasons, the public also has an interest to take part in the discussions. The question of food safety attracts attention since it concerns public health. We do not seem to escape that politics might be involved in everything.

Greenpeace argue that lack of labelling and the fact that so many foods are being introduced will leave the consumers unable to exercise free choice.<sup>136</sup> According to the study published by the Food Safety Department of the WHO, some form of mandatory labelling standards for foods produced using gene technology, had been adopted or planned by over 30 countries worldwide in 2004. These standards generally require a declaration of health and safety characteristics brought by the GM product, as well as an identification of the use of gene technology in the food production. The words “genetically modified” are often required to be used in association with the name of the food or ingredient.<sup>137</sup>

Concerning the choice of farmers in developing countries, it could be argued that farmers always have the choice whether or not to buy improved varieties from multinational corporations and that companies that invest in developing a product or technology should get paid for their creativity, capital risk-taking and hard work.<sup>138</sup>

## 6.2 The capacity issue

The question of national capacity concerning GM food is multidimensional. Originally, my concern was the national capacity in the developing country of domestic production under a compulsory licence. Or, more accurately, the lack of domestic production capacity. However, the capacity issue involves many other aspects, such as the status of regulations, institutional power, human resources and financial position.

In general, the food protection systems in developing countries are inadequately developed, and less organised than in most developed countries. No more than ten developing countries have implemented national biosafety laws.<sup>139</sup> The capacity needs in terms of food safety can be

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<sup>135</sup> Toke, p. 31.

<sup>136</sup> Greenpeace Agriculture, *Public Concern About Genetic Engineering*, [www.farmingsolutions.org](http://www.farmingsolutions.org) (retrieved 2006-12-13).

<sup>137</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 50.

<sup>138</sup> Crop Sector Conference, chapter 2.

<sup>139</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 26-27.

summarised as containing (1) basic infrastructure; (2) national food strategy; (3) food legislation and regulatory framework; (4) food inspection services; (5) food control laboratories and equipment; and (6) implementation of food quality and safety assurance systems.<sup>140</sup>

In order to make decisions on the safety of GM food, the government needs to be informed of the risks. Since developing countries have limited expertise in the required field of science, this could entail different consequences. If a biotechnology developer is engaged in the risk assessment, a potential conflict of interest could occur. Another point is that the biosafety committees often are recruited on voluntary basis, the people involved might therefore only feel a limited responsibility for the task.<sup>141</sup>

### 6.3 Ethical concerns

Food is a part of cultural identity and societal life and has a religious significance to people. That is why gene modification may meet social resistance. A global economy is emerging, but not necessarily a global society.<sup>142</sup>

According to the Food Safety Department Study, the reason for the relatively high resistance to GM food is not primarily lack of information. A study has shown that people do not react so much to genetic modification as a specific technology, but rather to the context in which GMOs are developed and the purported benefits they are to produce.<sup>143</sup> GMOs signify something unnatural and the very opposite development to the trend of organic agriculture. The opposition to GM crops and foods has as much to do with social and political values as with concerns about health and safety. We are, for instance, experiencing a growing consumer awareness and farmers fear an increasing dependency on multinational companies. The concerns relate to values and priorities such as the type of environment people want, the role of biodiversity, tolerance of risk and the price people are willing to pay for regulation. Some oppose GMOs symbolic for a larger opposition to the invasion of market forces, creating a world ruled by money and with little consideration for historical traditions, cultural identities and social needs.<sup>144</sup>

We might see an indifference and growing acceptance of GM food, or we might see a growing consumer awareness leading to a stronger consumer resistance.<sup>145</sup> During the past decade, organic food has become a growing notion in the food industry, calling for a consumer awareness of what we buy and what we eat and the consequences of our choice of food.

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<sup>140</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 26.

<sup>141</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 27.

<sup>142</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 56.

<sup>143</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 49.

<sup>144</sup> *Modern Food Biotechnology, Human Health and Development*, 2005, p. 49.

<sup>145</sup> Toke, p. 27-29.

# 7 Conclusions

## 7.1 Predicting no compulsory licensing of GM food

In spite of the Doha Declaration and the good intentions of facilitating compulsory licensing under the TRIPS Agreement, I believe that very few, if any, compulsory licences on GM food (or food products) will be granted in the foreseeable future. I base this judgment on various grounds.

The Doha Declaration was a response to the concerns about the AIDS pandemics and access to essential medicines in poor countries that are facing a public health emergency. Up until then, there had been uncertainties surrounding the use of the compulsory licensing system, even related to the acute AIDS situation in many countries and very few licences had been granted. The Declaration is an essential statement of a will to support the countries in need but it is unclear if we will see a boom of compulsory licences of AIDS medicines. What we might see is that the mere threat may play a strategic role in the negotiations of commercial agreements. This role is not to be underestimated. It might lead to an increasing number of licences, or at least licences that are more favourable to the developing country. Nevertheless, it seems unlikely (but I admit, not impossible) that GM food will rise to the same level of importance as AIDS drugs.

We know for a fact that few compulsory licences have been granted. This suggests two things. *First*, it implies that there is no need for compulsory licences. The country might not possess the proper tools to profit from a compulsory licence and thereby, another solution is pursued. This “no need” may in this, and similar, situations be created, meaning that there is a need for some sort of remedy to a problem, but because of a non-access the need is repressed. If there is a request of a patent protected product, agreements on commercial terms are being established. It is premature to discuss to what extent commercial agreements concerning GM food may fail, resulting in compulsory licensing. *Second*, it implies that the developing country face institutional or regulatory deficiencies, thereby failing to provide the opportunity of compulsory licensing. Either this is a question of prioritisation, or it is a lack of a sufficiently developed legal system.

When discussing compulsory licences, it is natural to think in terms of pharmaceuticals, because it is in that field that we have seen a crucial need for the advances in biotechnology. As I mentioned, GM food is not of the same dignity as those pharmaceuticals, and the fact that so few compulsory licences have been granted in that field, I draw the conclusion that the prognosis of the future for compulsory licences of GM food is quite bad. The Doha Declaration was designated to combat health problems due to

epidemics, by facilitating access to medicines. Concerning the supplying the developing world with GM food, the question is not access per se, but a choice between GM and non-GM food. There is no such justification choosing GM food, at this moment.

## 7.2 GM food in the developing world – the broader picture

While discussing the appropriateness of GM food in the developing world, we have to look at several issues that are interacting, to see the whole picture. What the issues have in common is that they all are related to development, which means that they are not constant and will, by definition change. This change may either be deliberate or as an effect to other factors. We can, in other words, chose, more or less, which we want to change. This is of course nothing new, but it might be worth to think about, as a means of prioritising.

The demographic issue of *human population growth* is a neutral fact. I do not consider this to be worth controlling, that is why I do not place any judgment on the occurrence of that fact. The question of family size lies within the private sphere. I do not say that it is impossible to control (as it has been done in China), but for now, I prefer to focus on other issues. It is slightly beside the point, but I believe that the population growth is merely a consequence of other factors, and that it will stabilise in the future, when other changes have taken place.

*Globalisation* is an issue that I find is positive as a fact and as a possibility, but that has entailed both positive and negative consequences. I believe that globalisation is an asset, but that we must chose carefully how to use it correctly. The situation is the same for the development of *information technology*. There are some negative consequences but the positive ones are more valuable. The benefit of both these developments is the possibility of sharing information. Two other issues, relevant to the subject, but rather unsound and highly unwanted, are *the pressure on natural resources* and *human created environmental changes*. These are complex issues, results of the western industrialisation, but they are also associated with our lifestyle and every day habits. I believe that we are learning from our mistakes and can improve the conditions of our industries to decrease the environmental pollution. A question, in relation to this, is how we teach or assist the developing countries to prevent them from making the same mistakes as the developed countries have made. International agreements and collaborations are emphasising the need for a sustainable development. Is the transfer of technology from the developed world to the developing world the answer? Biotechnology? GM food through compulsory licensing? I will return to this later on. Another issue, connected to the previous ones, is the *industrialisation of agriculture*. It is a positive type of development because it has rendered the agricultural industry more effective. However, using the wrong means of industrialising has contributed to negative environmental

effects. Farming in developing countries will profit from efficiency promoting measures of the right type, including decent tools and machines, provided that a sustainable development is aimed.

*New biotechnologies* constitute the last issue to frame this multifaceted subject, and the question is: Are they the solution? My opinion is that the research and developments in the field of biotechnology are very valuable and of great potential. Discoveries and life-saving medicines of our time owe practically everything to advances in biotechnology and I believe in future continued progress in this field. However, I do not believe that imposing, by any means, GM food on developing countries relieve the hunger problems. There are other ways to assist the developing world. But before I look into these alternative methods, I shall explain a few reasons why imposing GM food on the developing world is not appropriate.

The discussion has circulated around the prophecy that GM food will alleviate hunger in the developing world. I ask myself why the focus is on GM food especially, and not on non-GM food. I do not find any reason for compulsory licensing of GM food being a better alternative than providing, in some way, non-GM food. Why go through the trouble of lengthy research work resulting in a genetically modifying a crop, when all the farmers in developing countries need is *a* crop. I do see the benefit of increasing the nutrition values in some major crops and I do not oppose continued research, on the contrary, I believe that we have much to gain from this, however, for the moment, there is no specific demand, nor need, for the type of GM food that we see on the market today.

There is also the risk of environmental and biodiversity impact that should not be neglected. Imposing new varieties on nature is close to circumvention of evolution. Evidently, new varieties do develop naturally, but with the help of biotechnology, it is happening at a much faster rate.

Another important aspect of compulsory licensing GM food, which applies to other areas of biotechnology as well, is the reinforcement of dependency of the developing countries on the developed world. A country lacking domestic production possibilities rely on imports, as we have seen in the case on Brazil. This does not give any incentives for the country to develop, which is opposite to the entire idea of globalisation, balanced IPRs and sustainable development. On the contrary, we want to enforce independence and self-sufficiency within the (local) community or region. This gives a more secure and stable situation, where the members of the community have control, which also is a strong motivation and gives incentives to achieve well. It is for this reason unwise to supply the developing world with a product. We should instead supply them with tools and the knowledge so that they can produce themselves.

Another way of promoting scientific development in developing countries may be through collaboration between the public and private sector, both on a national and on an international level. Although, there is a risk involved if

the public sector in the developing country and multi-national corporations cooperates, something that would not favour small farmers in the developing countries. The ideal, in promoting the technological development would be that developed countries should support public science with the idea that the biotechnology products and processes obtained could be transferred free of charge to developing countries, at least for a transitional period of time, and without the intention to undermine the whole concept of IPRs.

### **7.3 Concluding the conclusion**

Three institutions regulate the distributive aspects of the commercial use of biogenetic resources and the related traditional knowledge. Intellectual property rights, national and regional access and benefit sharing regimes, and bioprospecting contracts. In the field of plant genetic resources for food and agriculture, IPRs might not be the most important in terms of influencing the way benefits are generated and distributed, as wished for when IPR originally was introduced. When searching for other ways to reach the desired results of a working system of compulsory licensing, solutions are often found “outside” the legal system. This is an interesting observation because that means that the legal framework of IPR has lagged behind or using the wrong instruments and is unable to meet the problems of the world today. We are aware of differences in legal traditions between the developed and the developing world, in many cases marked by historical events with colonial laws being imposed in several layers in the (written or oral) legal system of old colonies in the developing world. There are many arguments as to why the IPR system is unsuitable for all the countries of the world, one can only observe the state of the technical development of today to realise that the system favours the technically advanced developed countries.

### **7.4 Methodical retrospection**

In the introductory chapter, I discussed the methods I intended to use while studying my subject. In the discussion on the morality and ethical correctness of compulsory licensing of genetically modified plants, both a philosophical method and a law and sociology method was to be used. Being at the end of my work, I realise that a purely philosophical method never was applied on the question. Clearly, a sociologically influenced examination does not exclude the philosophical perspective, since sociology is a broad concept and used for studies of society and human social interaction. The dynamics and dialogue of that human interaction is to a large extent a result of different philosophical attitudes in the fundamental philosophical questions on the best way to live. Nevertheless, a philosophical study involves a certain abstraction and driving questions to an isolated theoretical extreme. This I have not been able to do, probably because of the unapparent and far-fetched, somewhat fictitious cases that this requires, leading me too far from my intended focus.

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