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THE TRAGEDY OF THE ANTICOMMONS IN BIOTECHNOLOGY

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"Universities are the cathedrals of the modern age. They shouldn't have to justify their existence by utilitarian criteria.”

-David Lodge

LIST OF ABBREVIATIONS

§	Section
Amend.	Amendment
Art.	Article
CEO	Chief Executive Officer
Cf.	Confer
DMCA	Digital Millennium Copyright Act
e.g.	Exempli gratia
E.U.	The European Union
ed.	Editor
Eds.	Editors
EPC	European Patent Convention
EPO	European Patent Office
EST	Expressed sequence tag
E.U. Guidelines	Commission Notice 27/04/2004, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, 2004 O.J. (C 101).
i.e.	Id est
Id.	Idem
INS	International News Service
MAD	Mutually assured destruction
NIH	National Institute of Health
PPI	Property preventing investment
R&D	Research and development

RTLA	Reach-through license
SARS	Severe acute respiratory syndrome
SNP	Single nucleotide polymorphism
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
U.S.	The United States
U.S. Const.	United States Constitution
U.S. Guidelines	1995 Antitrust Guidelines for the Licensing of Intellectual Property
U.S.C.	United States Code / The Code of Laws of the United States of America
USPTO	United States Patent and Trademark Office

INTRODUCTION

The typical European, or more strictly, Polish reader may not be used to this style of academic writing. The author has used a more American approach in creating this thesis. I have followed the guidelines of *The Redbook*[1] written by Bryan A. Garner for directions concerning style. For a manual on footnotes I have used *The Bluebook*[2]. Both sources are recognized authorities in the U.S. as far as academic legal writing is concerned. Thus, the European reader may encounter certain peculiarities, which she may not be used to, especially a large amount of citations, and a different structure thereof. Nevertheless, as Professor Fred Rodell once said: "Every legal writer is presumed to be a liar until he proves himself otherwise with a flock of footnotes."[3]

On a more personal note, I would like to underline that I am writing this thesis at a very fascinating moment. The topic of the tragedy of the anticommons still seems very fresh. And what has contributed to this freshness is the case of *Stanford v. Roche*[4]. Therein, Justice Breyer's and Ginsburg's dissent seems to scream out the idea of the article by Heller and Eisenberg, which is at the heart of this thesis. It may be bold to say such a thing, but being able to see in person the U.S. Supreme Court present the decision and being able to read it immediately after its publication, has inspired me to add my own small theory in the thesis concerning an additional image of the tragedy of the anticommons.

The approach applied in this thesis is a mixed one. It focuses the analysis on the U.S. legal system. Therefore, U.S. law will be the dominant theme of this thesis. Nevertheless, because the tragedy of the anticommons is an international concern, the thesis also endeavors to incorporate an analysis of certain E.U. legal issues. The approach however is not a strictly legal one, because in many parts an empirical approach is applied. Thus, the thesis should not be a complicated read.

The thesis is divided into five major parts. Because the tragedy of the anticommons is at its core, an economic problem, in Part I, I will present a short introduction into economic analysis, and one of its most important theories – the Coase theorem. After the introduction to certain economic principles, Part II will focus on the economic aspect of intellectual property. Later the tragedy of the commons will be presented,

[1] THE REDBOOK: A MANUAL ON LEGAL STYLE (Bryan A. Garner ed., 2nd ed.).
[2] THE BLUEBOOK: A UNIFORM SYSTEM OF CITATION (Columbia Law Review Ass'n et al. eds., 19th ed. 2010).
[3] REDBOOK, *supra* note 1, at 136.
[4] *Bd. of Trustees of Leland Stanford Junior Univ.* v. *Roche Molecular Sys.*, Inc., 563 U.S. ___ (2011).

since it is the mirror-image theory to the tragedy of the anticommons. Part III will be an introduction to the tragedy of the anticommons from a more theoretical standpoint. Part IV on the other hand, will focus on the facts and the law, which concerns the tragedy of the anticommons strictly in biotechnology, beginning with the Bayh-Dole Act. This part will also highlight the basics of patent law in the U.S. and the E.U.. Subsequently, the analysis will focus on biotechnological inventions in general. Further, the controversy over the patenting of genes will be discussed. Finally, the issue of pharmaceuticals will serve as a summary of the chapter. The last part, Part V, will be an analysis of the controversies behind the tragedy of the anticommons. It will, at the beginning, discuss the debate over the existence of the tragedy. And at the end, two methods of fending the tragedy off will be presented: market-based and legislative.

I. THE BASIC CONCEPTS OF LAW & ECONOMICS

The twilight where law and economics meet has been the domain of the so called economic analysis of law, or simply the law and economics movement. An explanation of what the tragedy of the anticommons is should be preceded by an explanation of what that school of legal thought is all about. The reason for this is that the mentioned tragedy is, in essence, an economic issue. Economic analysis is also a very American method of handling legal problems, especially since the groundbreaking case of *United States v. Carroll Towing Co*.[5] in which Judge Hand employed "an algebraic cost-benefit test for determining negligence."[6] In summary, economic analysis is invariably intertwined with the topic at hand, as it is the United States where most of the literature on the tragedy comes from.

It further seems that a brief explanation of such a vast field of research is a painstaking task. Therefore, not everything, not even a fraction most probably, of what economic analysis deals with will be mentioned. Special emphasis however will be put on rationality and the Coase theorem, as these two aspects are immensely important when discussing the tragedy of the anticommons. Their description is a necessity, because the importance of the two occurs in the heated debates on the existence of the tragedy.

1. ECONOMIC EFFICIENCY AND RATIONALITY OF THE HOMO OECONOMICUS

Economic analysis is centered around one important principle, namely around the *rational-choice theory*.[7] The theory has its roots in the philosophy of Jeremy Bentham and Gary Becker.[8] It stands for the notion that "man is a rational utility maximizer in all areas of life."[9] People maximize their utility, because maximization, according to economists, is rational.[10] Thus, man is often referred to by economists as the *homo oeconomicus*.[11] A ramification of the said axiom is that people respond to incentives by

[5] *United States v. Carroll Towing Co.*, 159 F.2d 169 (2d Cir. 1947).
[6] Larry L. Chubb, *Economic Analysis in the Courts: Limits and Constraints*, 64 Ind. L.J. 769, 769 (1989); *see also* RICHARD. A. POSNER, ECONOMIC ANALYSIS OF LAW 168-169 (Vicki Been et al. eds., Wolters Kluwer Law & Business, 7th ed. 2007).
[7] POSNER, *supra* note 6, at 3.
[8] *Id.* at 4.
[9] *Id.*
[10] ROBERT D. COOTER & THOMAS ULEN, LAW AND ECONOMICS 15 (Peason Addison Wesley, 4th ed. 2004).
[11] JERZY STELMACH ET AL., DZIESIĘĆ WYKŁADÓW O EKONOMII PRAWA 18-19 (Katarzyna Rybczyńska ed., Oficyna a Wolters Kluwer business 2007).

modifying their behavior, so as to increase their satisfaction.[12] Further, to increase satisfaction means to increase one's utility function, or in other words, choose the better alternative.[13] The rationality principle has however been criticized by the so called behavioral economics movement.[14] The movement postulates that "assumptions about behavior should accord with empirically validated descriptions of actual behavior."[15] Behavioral law and economics may be able to explain certain issues as to the roots of the tragedy of the anticommons.[16] This will be mentioned later.

Coming back however to the pro-rationality faction of law and economics. This classic economic analysis movement derives three fundamental concepts from the rational choice theory: the law of demand, opportunity costs, and the principle that resources gravitate to their most valuable use, if voluntary exchange is permitted.[17] These concepts are at the foundation of economic analysis. Although there is a plethora of other concepts, which are encompassed by this school, it will be sufficient to describe the three abovementioned principles before delving deeper into the issue of the tragedy of the anticommons.

The law of demand is in more professional terms "the inverse relation between price charged and quantity demanded."[18] It operates under the presumption that consumers seek substitutes in the event of an increase in price.[19] One may put forward the following example:

> If the price of steak rises by 10¢ a pound, and if other prices remain unchanged, a steak will now cost the consumer more, relatively, than it did before. Being rational self-interested, the consumer will react by investigating the possibility of substituting goods that he preferred less when steak was at its old price but are more attractive now because they are cheaper relative to steak.[20]

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[12] POSNER, *supra* note 6, at 4.
[13] COOTER & ULEN, *supra* note 10, at 15.
[14] *See* Reza Dibadj*, Regulatory Givings and the Anticommons,* 64 Ohio St. L.J. 1041, 1089-1092 (2003).
[15] *Id.* at 1089 (*quoting* Christine Jolls et al., *A Behavioral Approach to Law and Economics*, 50 Stan. L. Rev. 1471, 1489 (1998)).
[16] *Id.* at 1089-1092.
[17] POSNER, *supra* note 6, at 4-9.. *But cf.* COOTER & ULEN, *supra* note 10, at 15 (describing as the fundamental concepts of law and economics maximization, equilibrium, and efficiency).
[18] POSNER, *supra* note 6, at 4.
[19] *Id.*
[20] *Id.*

Whether the consumer will indeed find a suitable substitute steak will chiefly depend on that consumer's individual preferences.[21] These are organized in a rational fashion, as "[c]onsumers are assumed to know the things they like and dislike and to be able to rank the available alternative combinations of goods and services according to their ability to satisfy the consumer's preferences."[22] For preferences to be rational, they need to be: *complete* (the consumer has to be able to rank all and every good), *transitive* (the preferences should not be circular), *reflexive* (the good should be at least as good as itself).[23] The law of demand becomes important when analyzing the influence of opportunity costs.

The economic concept of cost states that "a cost is incurred only when someone is denied the use of a resource."[24] People factor in opportunity costs while making decisions.[25] Thus, when price is above opportunity costs, this works as an incentive for the production of a good.[26] This in turn enables the law of demand to adjust the prices (i.e. lower them) due to the increase in production.[27]

The last concept is the notion that through a process of voluntary exchange, resources gravitate to their most valuable use. This notion is connected with the Coase theorem, which will be mentioned later. Sufficed to say however, the third principle is also tightly associated with efficiency, since resources are used in an efficient fashion when their value is highest.[28] And it is in turn highest when the resources are in the hands of the individual who is willing to pay the highest amount for that resource.[29]

Moreover, there are various approaches to efficiency. The two most relevant ones are Pareto efficiency and Kaldor-Hicks efficiency.[30] The first occurs when "it is impossible to … make at least one person better off (in his own estimation) without making another person worse off (again, in his own estimation)."[31] Thus, after a Pareto improvement occurs, nobody is worse off.[32] The second, also called potential Pareto

[21] *Id.* It may also depend on a number of other variables, e.g. whether the sellers will decrease the price.
[22] COOTER & ULEN, *supra* note 10, at 22.
[23] COOTER & ULEN, *supra* note 10, at 22.
[24] POSNER, *supra* note 6, at 6.
[25] *Id.* at 8.
[26] *Id.*
[27] *Id.*
[28] *Id.* at 9.
[29] *Id.*
[30] *See id.* at 12-13; *see also* COOTER & ULEN, *supra* note 10, at 16-17.
[31] COOTER & ULEN, *supra* note 10, at 16-17.
[32] POSNER, *supra* note 6, at 12.

efficiency, is an approach that allows "[t]he winners to compensate the losers."[33] This does not however mean that they are obligated to do so.[34]

It is the sphere of obligations to do something that will become a hot topic in the debate over whether and if so, then how to, battle the tragedy of the anticommons. As mentioned, economic analysis presupposes that the greatest efficiency takes place when voluntary exchanges take place.[35] Thus, from a classic economic standpoint, parties should not be obligated to transfer resources. Transactions therefore, should not be forced. The issue of the freedom and efficiency of transactions should become more clear when discussing the Coase theorem.

2. THE COASE THEOREM

The issue of the tragedy of the anticommons seems to revolve in a major part around the Coase theorem. This is due to the fact that the theorem is a derivative of one of the founding principles of law and economics, i.e. the existence of opportunity costs.[36] It is also directly connected with the last principle concerning the allocation of resources towards their most efficient use. It is best to analyze this theory on the famous rancher-farmer example:

> A cattle rancher lives beside a farmer. The famer grows corn on some of his land and leaves some of it uncultivated. The rancher runs cattle over all of her land. The boundary between the ranch and the farm is clear, but there is no fence. Thus, from time to time the cattle wander onto the farmer's property and damage the corn.[37]

One may ask the question about what kind of law is better in this situation. But the gist of the matter here lies in the notion that this is irrelevant, because the entitlement will always gravitate towards the person who values this entitlement the most. Hence, regardless of the initial allocation of a right, or regardless of the legal rule, that right will end up with the person who is willing to pay more for that right.[38] Therefore, the legal rule is what encourages transactions to take place.[39] To reframe the issue,

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[33] *Id.* 13.
[34] *Id.*
[35] *Id.* at 9.
[36] *See id.* at 7 ("The most celebrated application of the concept of opportunity cost in the economic analysis of law is the Coase Theorem.").
[37] COOTER & ULEN, *supra* note 10, at 85-86.
[38] *See id.* at 86.
[39] *See* Dibadj, *supra* note 14, at 1113.

property rights are considered to be dispensable.[40] The most important ingredients needed for an efficient flow of resources are enforceable contract rights.[41] But there is an ingredient, which this formula is purposefully lacking, i.e. transaction costs. Transaction costs are the costs of transferring property rights.[42] They include "the costs of communicating, … impediments to bargaining."[43] In simple words, transaction costs may entail a plethora of factors, e.g. travel costs, the costs of hiring negotiators, but also time, or the costs of the imperfections of the human language. All of these costs are not taken into account in accordance with this interpretation of the Coase theorem.

Coase's theorem however is not as straightforward as it may seem at first glance. Namely, two interpretations with violently different implications emerged. These will be of particular importance when analyzing patent law in general. The first and most widely-known was already discussed. It simply states that:

> [I]f transactions are costless, the initial assignment of a property right will not affect the ultimate use of the property.[44]

This interpretation has recently come under heavy fire, as it is said to underestimate the importance of transaction costs and the initial allocation of rights.[45] The Coase theorem however has a different aspect. Over the years of being interpreted by scholars, another interpretation has emerged, stating that:

> When transaction costs are high enough to prevent bargaining, the efficient use of resources will depend on how property rights are assigned.[46]

Hence, what is important to bear in mind are the two drastically different interpretations. The Coase theorem becomes a relevant issue in the debate over the existence of the tragedy of the anticommons, or how society can face it. Should society create

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[40] WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW, 14 (The Belknap Press of Harvard University Press 2003) ("When transaction costs—which in general, though not in every case, rise with the number of contracting parties—are low, Ronald Coase's well-known analysis of transaction costs implies that enforceable contract rights are all that society needs, beyond some underlying set of entitlements so that the parties have something to contract about, to attain optimal use and investment").
[41] *Id.*
[42] *Id.* at 16.
[43] COOTER & ULEN, *supra* note 10, at 88-89.
[44] POSNER, *supra* note 6, at 7; *see also id.* at 89.
[45] *E.g.,* Clarisa Long, *Proprietary Rights and Why Initial Allocations Matter*, 49 Emory L.J. 823 (2000).
[46] COOTER & ULEN, *supra* note 10, at 89.

proper entitlements[47], or adopt an approach in accordance with the classic interpretation of the Coase theorem[48]?

The first interpretation has been fervently criticized, and views favoring the second interpretation have become stronger.[49] Extremely powerful views concerning this topic emerge in the field of patents in the biomedical industry.[50] The reason for this is that further research is built upon preceding discoveries, and that certain patents can cover "research results so basic that no commercial end-product is currently available."[51] Thus, transaction costs become a major issue in biomedical patents, especially their licensing.[52] There are various costs that may prevent the patent from being used by the person who values it the most, because the transaction costs of reaching a license agreement would be prohibitively high.[53] The costs include above all others: the costs of license searching, negotiation costs, the costs of enforcing the terms of the contract, etc.[54] These costs become even higher when the researcher needs to obtain multiple licenses, e.g. for multiple gene fragments.[55] This is the juncture where the Coase theorem meets the tragedy of the anticommons. Although it will be discussed later, it needs to be said here that the tragedy of the anticommons is an additional cost, which works against the first interpretation of the Coase theorem. The absence of transaction costs is an axiom that is unworkable, and reasonable players must factor them in.[56] But there is also the problem of reasonable risk-assessment – something that should theoretically not be a bother according to the first interpretation.[57] Namely, in the context of patents, there is a "severe and intractable lack of knowledge by all parties to the transaction regarding the fundamental value of the resource changing hands."[58]

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[47] *See* Long, *supra* note 45.
[48] Yahong Li, *Human Gene Patenting and Its Implications for Medical Research*, *in 2* INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE, PATENTS AND TRADE SECRETS 347, 366 (Peter K. Yu ed., 2006).
[49] *See* Long, *supra* note 45, at 827.
[50] *Cf. id.* at 823-824..
[51] Long, *supra* note 45, at 823, 824 (*noting* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property and the Norms of Science*, 94 Nw. U. L. Rev. 77, 123 (1999) ("[S]ome of the inventions on which patents are being sought are so removed from commercial application that further basic research will be necessary to identify fully their potential uses.").
[52] *See id.* at 827.
[53] *See id.* at 827-828.
[54] *Id.*
[55] *Id.* at 829.
[56] *See id.* at 831.
[57] *See id.* at 833.
[58] *Id.*

There is also one more issue concerning the third principle (the principle that resources tend to gravitate towards their most valuable use) and the Coase theorem. It is a psychological one. Namely, empirical studies suggest that initial entitlements matter from a psychological standpoint, even in conditions closely resembling the conditions of the first interpretation.[59] A notable experiment serves as an example:

> [H]alf the students were given … coffee mugs…. Markets were conducted and mugs bought and sold. … [T]he assignment of property rights had a pronounced effect on the final allocation of mugs. The students who were assigned mugs had a strong tendency to keep them. Whereas the Coase theorem would have predicted that about half the mugs would trade (since transaction costs had been shown to be essentially zero …, and mugs were randomly distributed), instead only fifteen percent of the mugs traded. And those who were endowed with mugs asked more than twice as much to give up a mug as those who didn't get a mug were willing to pay.[60]

An explanation for this is the so called *endowment effect*, which is part of a broader phenomenon called *loss aversion* – "the idea that losses are weighted more heavily than gains."[61] Such a notion casts doubt on the axiom of the *homo oeconomicus* and implied that human beings possess bounded rationality.[62] This notion is an important one, as will be explained later when discussing the tragedy of the anticommons.

In light of the second interpretation of the Coase theorem various solutions have been suggested. These include an approach to recognize the importance of initial entitlements and modify them accordingly.[63] An alternative solution is to recognize a liability rule as an alternative to an entitlement rule.[64] At this juncture it is not the solution that is relevant but the problem. There is a visible tension between the two interpretations of the Coase theorem. This tension is visible, albeit in the background, in the debate over the tragedy of the anticommons.

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[59] Christine Jolls et al., *supra* note 15, at 1483.
[60] *Id.* 1483-1484.
[61] *Id.* at 1484.
[62] *See id.* at 1477 ("Bounded rationality …, refers to the obvious fact that human cognitive abilities are not infinite").
[63] Long, *supra* note 45, at 836.
[64] *See* Dibadj, *supra* note 14, at 1113-1114.

II. THE ECONOMIC APPROACH TO INTELLECTUAL PROPERTY

Having described the most basic concepts of economic analysis, it becomes crucial to delve deeper into the field of intellectual property. Thus, before analyzing the problem of the tragedy of the anticommons it is still imperative to examine the field where this phenomenon occurs. This means that first and foremost the nature of information needs to be tackled from an economic standpoint. Then, as a prelude to the real problem, the mirror-image[65] tragedy of the commons will be described. Only then will it be possible to concentrate on the issue of the tragedy of the anticommons.

1. THE NATURE OF INFORMATION

One may raise that society is subject to a fallacy concerning intellectual property. This fallacy is to treat intellectual property rights like ordinary property rights pertaining to physical objects.[66] Thus, the problem for many is that treating a work of art like any other ordinary object, say a car or a house, is to obscure the real problems behind the intellectual property body of law.[67] This train of thought is most probably caused by a feeling of the highest entitlement of the creator towards her work. To battle such a misconception it becomes essential to distinguish between property law pertaining to physical objects and intellectual property, which pertains to information.

The common denominator of this analysis is naturally the term *property right*. This term is a bit of a problematic one, as with all fundamental legal concepts.[68] *Black's Law Dictionary* defines it as "[a] right to specific property, whether tangible or intangible."[69] It further defines *right* as "[a] legally enforceable claim that another will do or will not do a given act."[70] Therefore, according to a simpler and clearer definition, a property right is "a legally enforceable power to exclude others from using a re-

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[65] Michael S. Mireles, Jr., *The Intended and Unintended Consequences of the Bayh-Dole Act, in 2* INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE, PATENTS AND TRADE SECRETS 283, 288 (Peter K. Yu ed., 2006); *Cf.* Michael Heller & Rebecca Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

[66] LANDES & POSNER, *supra* note 40, at 11.

[67] *Id.* at 13.

[68] *See* Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions As Applied in Judicial Reasoning*, 23 Yale L.J. 16, 21 (1913) ("[T]he tendency to confuse or b'end non-legal and legal conceptions consists in the ambiguity and looseness of our legal terminology. The word "property" furnishes a striking example. Both with lawyers and with laymen this term has no definite or stable connotation.").

[69] BLACK'S LAW DICTIONARY (9th ed. 2009).

[70] *Id.*

source."[71] This ability to exclude exists for various reasons. When it comes to law and economics, the relevant reason, or the *raison d'être*, for property rights is the reduction of transaction costs.[72] This is due to the historical background of awarding intellectual property rights, which will be mentioned when discussing the tragedy of the commons. Hence, the pertinent issue arises, i.e. whether awarding property rights also lowers transaction costs and therefore increases the effectiveness in the informational context. In other words, it needs to be answered whether intellectual property – or rather its enforcement - is costly or not. If it is, then the social value of these rights will be minimal, or even negative, indicating that its enforcement may be an unsound economic policy.[73]

Case law has dealt with the fallacy that was mentioned at the beginning of this chapter in various ways. It would be prudent to describe a twofold approach to this issue adopted by U.S. courts. The most representative case law on the subject are the cases of *International News Service v. Associated Press*[74] and *Cheney Bros. v. Doris Silk Corp*.[75]. The two approaches adopted in relation to intellectual property highlight the debate over the nature of this body of law nowadays.

The *Int'l News Serv.* ruling may be considered to be the simpler approach towards intellectual property. Justice Pitney tackled the issue of the nature of news articles concerning the First World War. Namely, at the beginning of the twentieth century, at the time the First World War was being fought, it was of particular importance for American news organizations to report on the war efforts in the quickest possible manner. One of the parties however, the International News Service (INS), was left in a handicapped position, since it was not allowed to use Alliance telegraph lines.[76] Hence, in order to battle this disadvantage, the so called Hearst Service (as the INS was known) reporters used bribes in order to gain news on the war.[77] The materials gained from such practices were subsequently altered and published.[78]

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[71] LANDES & POSNER, *supra* note 40, at 12.
[72] *Id.* at 12-13.
[73] *See id.* at 14 ("[I]f the costs of enforcing property rights are disproportionate to the value of the rights, or if the costs of appropriating someone's valuable good are prohibitive quite apart from any legal sanctions, the social value of property rights will be slight or even negative.").
[74] *Int'l News Serv. v. Associated Press,* 248 U.S. 215 (1918) (Brandeis J., Holmes J. dissenting).
[75] *Cheney Bros. v. Doris Silk Corp.*, 35 F.2d 279 (2d Cir. 1929).
[76] *See News Pirating Case in Supreme Court*, The New York Times, May 3, 1918, at 14, *available at:* http://query.nytimes.com/mem/archive-free/pdf?_r=1&res=9A07EED71F3FE433A25750C0A9639C946996D6CF, (last visited 26 April 2011).
[77] *See id.*
[78] *See id.*

Justice Pitney therefore faced the question of the property value of news.[79] In his ruling he adopted an unfair competition approach. This led him to consider news to be subject to a quasi property right. The decision stated:

> Regarding the news, therefore, as but the material out of which both parties are seeking to make profits at the same time and in the same field, we hardly can fail to recognize that for this purpose, and as between them, it must be regarded as quasi property, irrespective of the rights of either as against the public.[80]

In other words, Justice Pitney treated information more like a tangible item and created towards it the strongest of possible rights, i.e. a property right. It is therefore not surprising that this instigated a backlash in the form of a dissenting opinion by Justice Brandeis. In his opinion he recognized the danger of the creation of such a right by underlining that "[t]he creation or recognition by courts of a new private right may work serious injury to the general public."[81] He further argued that any such right should be narrowly tailored and its boundaries need to be clearly defined.[82]

A different view from Justice Pitney's was however adopted in the *Cheney Bros*[83] case. The case dealt with a silk manufacturer who seasonally introduced new patterns of its products into the market "designed to attract purchasers by their novelty and beauty."[84] The defendant took advantage of this situation and copied one of the plaintiff's pattern and sold it at a lower price.

The situation was similar to the one in the *Int'l News Service* case, as once again the court faced the question whether copying should be considered to be theft. This time however the court was presided by Judge Hand who was, at the very beginning mentioned as the judge who introduced an economic approach to law. The court therefore adopted a more economic approach having Justice Brandeis' dissenting opinion in mind.[85]

> To exclude others from the enjoyment of a chattel is one thing; to prevent any imitation of it, to set up a monopoly in the plan of its structure, gives

[79] *See id.*
[80] *Int'l News Serv.*, 248 U.S. at 236.
[81] *Id.* at 262-263.
[82] *See id*.
[83] *Cheney Bros. v. Doris Silk Corp.*, 35 F.2d 279, Circuit Court of Appeals, Second Circuit (1929).
[84] *Id.* at 279.
[85] *See id.* at 281 ("Indeed, we are not in any position to pass upon the questions involved, as Brandeis, J., observed in *International News Service v. Associated Press*.").

> the author a power over his fellows vastly greater, a power which the Constitution allows only Congress to create.[86]

The court's reasoning applied, in essence, a more policy-oriented approach. It is indeed true that Doris Silk did not put any effort into making its product; but the broader issue is whether this should be considered as *unfair*. In Judge Hand's opinion such treatment would be detrimental to society. This is closely related to the fact that Doris Silk's actions touch upon broader issues, i.e. the nature of information. The core of the problem is that it is hard to say for certain whether information is a private or public good.[87] It is considered to be a quasi public good.[88] This is due to the fact that there is no consumption rivalry over information, because it can be easily copied;[89] one can however exclude others from gaining access to it.[90]

Regardless of what approach one may consider to be more just, it is crucial to examine the economic approach in more detail at this point. The question therefore boils down to the issue of whether intellectual property rights in their current shape, or even in general are economically effective. From such a standpoint two stances on the issue arise. These may be considered to be a derivative of the abovementioned approaches. The first puts forward the notion that intellectual property rights should be broadened, because via maximum protection of an author's creations can new works come to be. This is the approach of the *Int'l News Service* case. The second states the opposite, i.e. that expanding the public sphere is the best approach towards inspiring creativity. This, on the other hand, is the *Cheney Bros.* case approach. The former attitude was criticized through the following example. Namely, if court decisions were to be protected under intellectual property rights and not be part of a commons, it would not likely increase their quality or quantity.[91] It would further even increase transaction costs for lawyers wishing to obtain these decisions.[92] What stems from this, maybe a bit

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[86] *Id.* at 280.
[87] *See* Wojciech Załuski, *Schemat ekonomicznego ujęcia prawa własności intelektualnej*, *in*, ANALIZA EKONOMICZNA W ZASTOSOWANIACH PRAWNICZYCH, 101, 102 (J. Stelmach & M Soniewicka eds., Oficyna 2007).
[88] *See id.* at 102.
[89] *Id.*
[90] *Id.*
[91] LANDES & POSNER, *supra* note 40, at 15 ("Judicial decisions are not copyrighted; they are all in the public domain and thus a "commons" available for all to use without a license. Because they are produced as a byproduct of the operation of a court system, it is unlikely that more would be produced if they were copyrighted. Nor is it likely that more would be better").
[92] *Id.* ("Most important, the transaction costs of obtaining licenses by the myriad of lawyers, litigants, judges, and law professors who make copies of judicial decisions would be immense").

humorous example, is that too much protection can breed large societal costs. These costs are: transaction costs, rent-seeking costs and protection costs.[93]

As mentioned earlier, transaction costs are costs of transferring rights.[94] They play a crucial role in adjusting the prices of goods and thus reflect the market-value of said products. If they are too high, these adjustments may lead to suboptimal results.[95] And indeed in the case of intellectual property they are high.[96] The reason for this once again brings back to the crux of the discussion about the nature of intellectual property. Namely, it is the difference between tangible and intangible objects, or rather the problem of identifying the property in question.[97] The common example is that of a picture.[98] The intellectual property right does not pertain to the canvas, frame, or paint but to "a nonmaterial object separate from the painting itself."[99] The high costs of defining these rights often concern costs associated with deciding on whether a right was infringed upon.[100] To put this in simple terms, it is problematic to determine whether a similar picture is a new work of art or a copy.[101] Thus determining theft of intellectual property brings back to the problems deliberated in the *Int'l News Service* and *Cheney Bros* cases.

The second of the mentioned costs is the cost of rent-seeking – an issue, which is relevant to the tragedy of the anticommons. Economic rent is defined as "a return over and above the cost of generating the return; it is pure profit."[102] The mentioned costs of endeavoring to obtain rent are often of a social nature.[103] In terms of intellectual property, rent-seeking is associated with the so called *patent race*.[104] In other words, the large investments put into the effort to acquire a property right, e.g. a patent, may be harmful

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93 *Id.* at 16-19.
94 *Id.* at 16.
95 *See* i*d.* ("If it is too high, a property right may prevent optimal adjustments to changing values.").
96 *Id.* ("Transaction costs tend to be high in the case of intellectual property even when there are only a few transactors, actual or potential, in the picture").
97 *See* i*d.* ("The reason is the frequent difficulty of identifying such property because by definition it has no unique physical site.").
98 *See id*.
99 *Id.*
100 *Id.* ("Such rights are difficult to define because while the original itself is a definite, visible, physical object, what we are calling "the picture" is not, so there might be a question whether something that looked very much like the original was a copy that infringed the copyright or an independent creation that merely resembled the original.").
101 *See id.*
102 *Id.* at 17.
103 *See id.*.
104 *See* i*d.* at 18 ("The legal protection of intellectual property gives rise to serious problems of rent seeking because intellectual goods are waiting, as it were, to be discovered or invented, just like the sunken ship whose owner has abandoned it. The term "patent race" has been coined to describe an intellectual property counterpart").

to society in the long-run. This is due to the fact that at the end of the day, the acquired patent may not prove profitable.[105] Thus, to take a step back, this may cause potential investors to withdraw from the investment.

The third cost is the cost of protecting intellectual property rights. Protection of said rights is considered to be a costly endeavor.[106] This again is due to the difference between a tangible item and an idea, the infringement of which is far more difficult to identify.[107] One of the major factors adding to the costs of protection is the fact that there is no crowding effect in the case of intellectual property, and thus use of intellectual property rights is much easier, as nobody interferes with one's use by others.[108] Therefore the increase of users does not breed any costs.[109] Such a notion simply means that the use of intellectual property is fairly easy by multiple entities, which is the core difference between an idea and e.g. a car.

The sheer fact that the use of intellectual property is costless is not enough due to the other side of the coin, i.e. the incentive to create and the fact that intellectual property rights are, as indicated above, more costly in general.[110] This leads to the notion of the so called *access versus incentives tradeoff*.[111] In other words, a balance must be struck between rewarding the creator and the social cost of limiting the public's access to information.[112] How this balance is struck is a very complex matter. In patent law for example, one way to limit the scope of the property right is the imposition of the nonobviousness requirement.[113] Another approach in striking the balance is via trade secrecy.[114] What is often the case is that even if intellectual property rights were nonexistent, then still progress would not be impeded, because a large amount of creativity is

[105] *Id.* ("The excess over the optimal investment, minus any social benefit produced by the additional investment, is the waste produced by rent seeking").
[106] *Id.* ("Intellectual property tends to be particularly costly to protect").
[107] *Id.* ("To trace the descent of an idea (or image, verbal formula, and so on), which has no spatial limits, is much more difficult.").
[108] *Id.* at 19 ("And so to the extent that the use of intellectual property by one person does not interfere with its use by others, there is no crowding effect that one might want to alleviate by imposing a price for such use.").
[109] *Id.* at 20 ("Often and not merely exceptionally, adding users will impose no costs on previous users of intellectual property.").
[110] *See id.* at 21.
[111] *Id.* at 20 - 21 ("[T]he "access versus incentives" tradeoff: charging a price for a public good reduces access to it (a social cost), making it artificially scarce ..., but increases the incentive to create it in the first place, which is a possibly offsetting social benefit.").
[112] *See id.*
[113] *See id.* ("An example is the requirement that an invention, to be patentable, must not be an obvious application or extension of existing technology. This requirement prevents the obtaining of a property right in circumstances in which deadweight loss and excessive rent seeking would be serious problems.").
[114] *See id.* at 22.

not influenced by property right incentives.[115] The works created in such a manner are not necessarily protected by intellectual property rights but "by the normal rights that people have to privacy and physical property"[116]. Finally, there is also the notion of governmental incentives. Because costs of creating a work are high while costs of duplication insignificant, then some introduce the idea that the state may provide grants for the creation of new information.[117]

All the mentioned economic aspects of intellectual property rights are more than a hypothetical concern when discussing the tragedy of the anticommons. The high costs of research and development coupled with the necessity for enabling the public to have access to crucial information is one of the core issues when it comes to the topic of this thesis. It therefore becomes the crucial issue of how to reconcile the said concerns and how to strike the *access versus incentives tradeoff*. At the heart of the matter is in essence the problem of how large the public sphere, or the commons, and the private sphere should really be. To understand the rationale behind the increase in protection of private property, the tragedy of the commons needs to be analyzed before an in-depth analysis of the tragedy of the anticommons can be introduced.

2. THE TRAGEDY OF THE COMMONS AND THE RATIONALE OF PRIVATE OWNERSHIP

To even start to define the tragedy of the anticommons, one has to begin with a brief analysis of an opposite problem. The said problem is called the tragedy of the commons and is naturally associated with commons property. Garrett Hardin, the creator of this term, used this term to explain the reasons for overpopulation, air pollution, and species extinction.[118] He achieved it by using a fitting metaphor to describe what the tragedy of the commons is.

> The tragedy of the commons develops in this way. Picture a pasture open to all. It is to be expected that each herdsman will try to keep as many cattle as possible on the commons. Such an arrangement may work rea-

[115] *Id.* ("Because the producers of intellectual property have these rights, a great deal of intellectual property would be created even if there were no property rights in intellectual goods as such. We know this because an enormous quantity (and quality) of intellectual property was produced before there were such rights and because even today a great deal of the intellectual property that is produced would be produced even if they did not exist").
[116] *Id.*
[117] *See id.* at 24 ("[I]n the absence of intellectual property rights either the intellectual property will not be created or the government may have to finance it through a system of grants or rewards to writers and inventors").
[118] Heller & Eisenberg, *supra* note 65, at 698.

> sonably satisfactorily for centuries because tribal wars, poaching, and disease keep the numbers of both man and beast well below the carrying capacity of the land. Finally, however, comes the day of reckoning, that is, the day when the long-desired goal of social stability becomes a reality. At this point, the inherent logic of the commons remorselessly generates tragedy. As a rational being, each herdsman seeks to maximize his gain. Explicitly or implicitly, more or less consciously, he asks, "What is the utility to me of adding one more animal to my herd?" This utility has one negative and one positive component.…
>
> [T]he rational herdsman concludes that the only sensible course for him to pursue is to add another animal to his herd. And another; and another… But this is the conclusion reached by each and every rational herdsman sharing a commons. Therein is the tragedy. Each man is locked into a system that compels him to increase his herd without limit—in a world that is limited. Ruin is the destination toward which all men rush, each pursuing his own best interest in a society that believes in the freedom of the commons. Freedom in a commons brings ruin to all.[119]

The moral of the story is simple: "[w]hen too many people share a single resource, we tend to overuse it."[120] The image presented is a so called *static property right*.[121] If the owners of such a right do not factor in the costs they impose on each over, then their property is prone to overuse.[122] The solution for the tragedy therefore is to entitle individuals with property rights, as it gives them the incentive to improve, conserve, and take care of their property.[123] Thus, awarding property rights serves as a stimulant for the reduction of transaction costs.[124] This is the so called *dynamic benefit* of property rights.[125] Hardin's article has been strongly criticized, especially on the grounds of its morally dubious ideas concerning human rights and the solution to overpopulation.[126] An even more serious blow towards the article is that "there is significant

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[119] Garrett Hardin, *The Tragedy of the Commons*, 162 SCI. 1243 (13 December 1968), *available at:* http://www.sciencemag.org/cgi/content/full/162/3859/1243. (last visited 1 August 2011).
[120] MICHAEL HELLER, THE GRIDLOCK ECONOMY: HOW TOO MUCH OWNERSHIP WRECKS MARKETS, STOPS INNOVATION, AND COSTS LIVES 1 (2008); *see also* Mireles, *supra* note 65, at 288 ("Garret Hardin's 'tragedy of the commons' theory holds that, if property is held in common, users of the property will not have an incentive to conserve the property and overuse will result."); LANDES & POSNER supra note 40, at 13.
[121] LANDES & POSNER supra note 40, at 12 (meaning that nobody can exclude others from the property).
[122] *Id.*
[123] *Id.* at 13 ("The dynamic benefit of a property right is the incentive that possession of such a right imparts to invest in the creation or improvement of a resource"); *Cf.* Mireles, *supra* note 65, at 288.
[124] *Id.* at 12-13.
[125] *Id.* at 13.
[126] Dibadj, *supra* note 14, at 1124 ("Indeed, he is perhaps using this concept as a rhetorical tool to further the disturbing argument that consumes the bulk of his essay-namely, that of restricting the freedom of individuals to breed.")

empirical evidence that a regulated commons can functions effectively."[127] Despite this however, Hardin's conclusions have nevertheless been intellectually expanded. Harold Demsetz analyzed the issue of the birth of private property by presenting it as the ramification of a transition from the commons system.[128] The prime example is that of the Native Americans:

> As the seventeenth century came to an end and the eighteenth began, the status of land along the eastern border that was later to separate Canada and the United States underwent a transformation from tribal-based collective ownership to family-based private ownership.[129]

The relevant issue concerning this development is why it happened. The answer to this question is of an economic nature. During the mentioned period the demand for fur increased in Europe, forcing the Native Americans to hunt more beavers.[130] Since the land belonged to no one, the hunters did not take into account the consequences of overhunting.[131] The demand for fur on the other hand, created an incentive to hunt more and more.[132] This does not however mean that the commons is an ineffective system. It best serves, or is even superior, when applied in a stone age based economy.[133] Nevertheless, the increase in demand changes the situation and the private property system becomes a better way of providing supplies. Because "land rights confer effective control,"[134] the owners of the land are no longer susceptible to the tragedy of the commons. From a historical perspective, "[t]he transformation to farming increased the practicality of private ownership."[135] The reason for this was that the privatization of land is simple, and thanks to this process families were able to earn their upkeep by creating surplus, which could subsequently be sold.[136]

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127 *Id.* at 1047.
128 *See* Harold Demsetz, *Toward A Theory of Property Rights II: The Competition Between Private and Collective Ownership*, 31 J. Legal Stud. 653 (2002).
129 *Id.* at 655-56.
130 *Id.* at 656.
131 *See id.*
132 *See id.*
133 *Id.* at 666 ("The setting for economizing decisions and actions could hardly have been more compact. Collective control not only was feasible, it also was likely to be superior to what could be achieved through a division of meager group assets into privately held subportions.").
134 *Id.* at 656.
135 *Id.* at 666.
136 *See id.* at 667 ("The amount of land required to sustain a family through farming was small enough in size and fixed enough in location to allow its policing by the family or families that worked it. Grain crops could be stored in amounts that exceeded immediate needs, and excess supplies could be transported across considerable distances without deteriorating.").

With the Native American example in mind, it becomes much easier to define how the tragedy of the commons works. Namely, the overuse of a resource creates an externality, i.e. "an effect on the production transformation opportunities facing others, such effect being a result of actions taken by someone who does not bear the value consequences of this effect."[137] According to a simpler definition, an externality is "[a] consequence or side effect of one's economic activity, causing another to benefit without paying or to suffer without compensation."[138] In the abovementioned example, an externality is "the neglected impact of hunting today on the cost of hunting tomorrow."[139] This rule is not only limited to hunting, but also to e.g. pollution.[140] The pollution issue however works differently, because "it is not a question of taking something out of the commons, but of putting something in."[141] Additional examples are easy to name. It is however sufficient to give a more universal definition of the tragedy of the commons:

> A tragedy of the commons can occur when too many individuals have privileges of use in a scarce resource. The tragedy is that rational individuals, acting separately, may collectively overconsume scarce resources. Each individual finds that she benefits by consumption, even though she imposes larger costs on the community.

At the very end, as an introduction to the next chapters, it seems prudent to show the relevance of this definition, and of what Hardin's pasture represents, in connection with intellectual property. In intellectual property, the pasture, or simply the commons, is the public domain.[142] These are a plethora of ideas, expressions, which are not patented or copyrighted.[143] What makes them however different from the pasture is that they cannot be worn out.[144]

It is the goal of the subsequent chapters to describe what may be happening to this intellectual property pasture today. The discussion however is not about whether a commons is hurtful. The problem is just the opposite, as according to the proponents of

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137 *Id.* at 656.
138 BLACK'S LAW DICTIONARY (9th ed. 2009).
139 *Id.*
140 *See* Hardin, *supra* note 119, at 1245.
141 *Id.*
142 LANDES & POSNER supra note 40, at 13.
143 *Id.*
144 *Id.* at 13-14.

the tragedy of the anticommons, "[p]rivatization can solve one tragedy but cause another."[145]

[145] Heller & Eisenberg, *supra* note 65, at 698.

III. DEFINING THE TRAGEDY OF THE ANTICOMMONS

Having discussed the basics of economic analysis, the economics of intellectual property law, and the tragedy of the commons, now comes finally the time to touch upon the issue of the tragedy of the anticommons. To understand how it works in reality, it is imperative to define it. The natural path to start that definition in this case is to first and foremost show how that term came to be devised. The journey at this juncture will lead to Moscow. After that a more theoretical approach will be adopted to present the roots of the tragedy.

1. MOSCOW STOREFRONTS

How the theory of anticommons property came to be is quite a riveting tale. The beginnings of the theory can be traced to Moscow. There, an assistant professor by the name of Michael Heller, noticed a peculiar phenomenon. During the Soviet Union's transformation into a market economy, Moscow was the subject of an infestation of small metal kiosks. Although "[o]ne promise of the transition to a free market was that new entrepreneurs would fill stores that socials rule had left bare,"[146] nobody was opening storefronts and a lot of spaces stood empty. After a more in-depth analysis, Heller reached the conclusion that a lot of entities and people were to blame, as they were preventing entrepreneurial Moscovians from using the empty spaces. But the real culprit was in fact property law.

> Empty Moscow storefronts are a stark example of anticommons property, a type of property regime that may result when initial endowments are created as disaggregated rights rather than as coherent bundles of rights in scarce resources.[147]

Heller made an obvious, but very important point. From a legal standpoint, property is considered to be a bundle of rights.[148] In light of this, anticommons property emerges when various owners possess different rights within the bundle.[149]

> A tragedy of the anticommons can occur when too many individuals have rights of exclusion in a scarce resource. The tragedy is that rational indi-

[146] Heller & Eisenberg, *supra* note 65, at 698.
[147] Michael A. Heller, *The Tragedy of the Anticommons: Property in the Transition from Marx to Markets*, 111 Harv. L. Rev. 621, 623 (1998).
[148] COOTER & ULEN, *supra* note 10, at 77.
[149] Dibadj, *supra* note 14, at 1049

> viduals, acting separately, may collectively waste the resource by under-consuming it compared with a social optimum.[150]

To shorten the definition, the anticommons theory holds that "if you grant too many rights in a particular piece of property, rights holders may block one another wherein no one party is able to effectively use the property."[151] Thus the tragedy occurs when a resource is underused as a result of multiple owners, each having a right to exclude another.[152] And indeed this was the case of Moscow and of ownership of socialist property, which "[i]nstead of assigning an owner to each object … created a complex hierarchy of divided and coordinated use of rights in the objects it defined."[153] This complicated structure of ownership was suddenly thrust into the market system, preventing its proper development.[154] Instead of creating a bundle of rights representing ownership, fragmented rights were left distributed to various stakeholders, which included, e.g. quasi-private enterprises, workers' collectives, privatization agencies, and local, regional, and federal governments.[155] The only way for those wanting to start a business was to circumscribe the terrible property system and go with the easy solution, i.e. open a kiosk.[156] The process of opening one was a lot simpler, as "[o]n the streets, no complex web of rights needed to be bundled. Instead, kiosk merchants had to bribe only a limited number of municipal officials and an easily identifiable criminal organization."[157]

Moscow may therefore be considered to be the birthplace of the anticommons theory. The tragedy of the anticommons however went much further than just being an explanation of the issue of the proliferation of kiosks; it nowadays tries to explain the proliferation of patents and the ramifications this carries. However, before the patent issue can be touched upon, it is crucial to identify what exactly the tragedy of the anticommons is without the Moscow context.

2. THE ROOTS OF THE TRAGEDY OF THE ANTICOMMONS

The core of the anticommons issue is not associated with the total halt of research and development. The gist of the problem is rather situated in the law and eco-

[150] Heller, *supra* note 147, at 677.
[151] Mireles, *supra* note 65, at 288.
[152] Heller & Eisenberg, supra note 65, at 698.
[153] Heller, *supra* note 147, at 629.
[154] *Cf. id.* at 629-630.
[155] Heller & Eisenberg, *supra* note 65, at 698.
[156] *Cf.* Heller, *supra* note 147, at 643.
[157] *Id*.

nomics' postulate of efficiency. Namely, the tragedy of the anticommons does not make itself known through a grinding halt of science, or production, but through an increase in transaction costs. The problem associated with this is that if transaction costs are high enough there is a threat of a halt of various undertakings. Thus scholars who do feel the threat of the tragedy of the anticommons underline that it may at the end of the day lead to a gridlock.[158] However, in order to trace how such a gridlock comes to be, still a more general picture is needed. The theory of law and economics, as well as the tragedy of the commons were already discussed. Hence at this juncture it seems crucial to analyze the theoretical underpinnings of the tragedy of the anticommons.

A. REGULATORY GIVINGS

The theoretical roots of the tragedy of the anticommons are traced by some to so called *regulatory givings*.[159] To understand what this term encompasses, it is crucial to introduce its mirror-image term, i.e. *regulatory takings*, a term used by the Fifth Amendment to the U.S. Constitution in the Takings Clause, which states:

> [N]or shall private property be taken for public use, without just compensation[160]

Takings is simply "government seizures of property."[161] A special type of takings is regulatory takings, in which government acts as a regulator and "imposes restrictions on what a person may do with his or her property."[162] Much has been written about the phenomenon of takings and it is not necessary to dwell on this issue in this thesis. What is far more relevant in the case at hand are givings, which are "government distributions of property."[163] This term, although not stated directly in the U.S. Constitution, is a logical extension of the Fifth Amendment rule.[164] The reason for this is that when a taking occurs so does a giving.[165] Moreover, a special type of giving – *regulatory giving* – is most important in the case of the tragedy of the anticommons. A regulatory giving occurs when "the state uses its regulatory power to enhance the value of cer-

158 HELLER, *supra* note 120, at 2.
159 *See* Dibadj, *supra* note 14, at 1045 ("[R]egulatory givings have the potential of creating an anticommons.").
160 U.S. CONST. amend. V.
161 Abraham Bell & Gideon Parchomovsky, *Givings*, 111 Yale L.J. 547, 549 (2001).
162 ALLAN IDES & CHRISTOPHER N. MAY, CONSTITUTIONAL LAW INDIVIDUAL RIGHTS 141 (Aspen Publishers, 5th ed. 2010); *see also* Barlow Burke & Joseph Snoe, Property 629-654 (Aspen Publishers, 3rd ed. 2008).
163 Bell & Parchomovsky, *supra* note 161, at 549.
164 *See id*. at 563.
165 *Id*.

tain private properties."[166] In other words, such a giving takes place when regulation goes "too far,"[167] i.e. when the government "bestows a disproportionate benefit on a class of private actors."[168] The disproportionate benefit in this context is such a group's enrichment at the cost of the general public.[169] The problem with regulatory givings is that they are subtle and seem benign.[170] Moreover, givings create the danger of positive externalities, if they are not accounted for.[171] What stems from this is the conclusion that "regulatory givings have the potential of creating an anticommons."[172] This is the point where the issue of the tragedy of the anticommons goes back to economic analysis and, to a degree, to the Coase theorem[173], because:

> Overlooking givings may cause a massive misallocation of resources, impose an enormous cost on the public, and create opportunities and incentives for political mischief.[174]

A misallocation of resources, or anticommons property, may be overcome by transferring rights, in accordance with the Coase theorem.[175] However, as has been already pointed out, the presence of transaction costs, cognitive biases, as well as strategic behaviors, makes this highly unlikely.[176]

B. THE HOHFELDIAN APPROACH

A more theoretical analysis of the problem of anticommons property is considered to be traceable to the legal scholar Wesley Hohfeld.[177] His reflections did not concern the tragedy of the anticommons directly but revolved on more general issues. The relevant part, concerning anticommons property, involved the definition of the terms *right*, *duty*, *privelege*, n*o-right*. All these terms constitute so called *jural correlatives*

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166 *Id*. at 551.
167 *Id*. at 563.
168 *Id*.
169 *Id*. at 553.
170 Dibadj, *supra* note 14, at 1046.
171 Bell & Parchomovsky, *supra* note 161, at 554; *see also* BLACK'S LAW DICTIONARY (9th ed. 2009) (explaining that a positive externality is an externality that benefits another, such as the advantage received by a neighborhood when a homeowner attractively landscapes the property).
172 Dibadj, *supra* note 14, at 1046.
173 As a reminder, this is due to the fact that the issue of efficiency also concerns the proper allocation of resources.
174 Bell & Parchomovsky, *supra* note 161, at 564.
175 Mireles, *supra* note 65, at 288.
176 *Id.* at 288; Heller & Eisenberg, *supra* note 65, at 698 ("In theory, in a world of costless transactions, people could always avoid … anticommons tragedies by trading their rights. In practice however, avoiding tragedy requires overcoming transaction costs, strategic behaviors, and cognitive biases of participants ….").
177 *See* Dibadj, *supra* note 14, at 1048 ("Strangely enough, anticommons can be traced backed to a theoretical article by Wesley Hohfeld")(*noting* Hohfeld, *supra* note 68).

and *jural opposites*.[178] The former is the relation between the terms *right* and *duty* and the relation between *privilege* and n*o-right*. Concordantly, *jural opposites* are the relations between *right* and *no-right*, *duty* and *privilege.* The following example helps explain these terms:

> [W]hereas X has a right or claim that Y, the other man, should stay off the land, he himself has the privilege of entering on the land; or, in equivalent words, X does not have a duty to stay off the place. […]
> Thus the correlative of X's privilege of entering himself is manifestly Y's "no-right" that X shall not enter.[179]

The latter relation is considered to be a relation similar to a commons.[180] This is due to the fact that, in the simplest of terms, "I have the privilege of walking on the sidewalk, and you have no right to tell me not to"[181]. Concomitantly, the former may be analogous to an anticommons, because "if you have a right to prevent me from hiking in the national forest, then I have a duty to stay off it"[182]. In light of the aforementioned, an anticommons may be defined "as a legal regime where the Hohfeldian right to exclude is created without granting the 'bundle of rights' that constitutes property. This, in turn, creates an underutilization of resources."[183]

C. Other Approaches to the Tragedy of the Anticommons

Regulatory givings and the granting of the right to exclude without an adequate bundle of rights are a creature of the legislature. Such a conclusion leads to the issue of the political machine. In the context of law and economics, the political sphere is the domain of the public choice theory. Therefore, from the standpoint of this theory, the roots of the tragedy are in governmental actions. In a nutshell, "[g]overnment bestows upon private economic actors rights short of property rights. In turn, these regulatory givings allow private parties to exclude others, holding up competition and diversity."[184]

A reason for why regulatory givings occur may be of a political nature, thus the public choice theory is put forward to try to explain this phenomenon.[185] The theory concentrates around the influence various factions have in pushing their agendas via the

[178] *See* Hohfeld, *supra* note 68, at 30.
[179] *Id.* at 32-33.
[180] *See* Dibadj, Reza, Regulatory Givings and the Anticommons, 64 Ohio St. L.J., 1041, 1048 (2003).
[181] *Id.*
[182] *Id.*
[183] *Id.* at 1050.
[184] *Id.* at 1103.
[185] *Id.* at 1063.

political machine.[186] By definition, government according to that theory "is merely a mechanism for combining private preferences into a social decision."[187] In the case of the occurrence of regulatory givings, these may arise because strong, influential, but not numerous, groups are better organized than multiple, numerous, but unorganized groups of interest.[188] An excellent example of such a strong group is the pharmaceutical industry.[189] Moreover, regulatory givings are extremely advantageous for politicians when being pushed through, and even more dangerous, because "they may produce winners without producing obvious losers, making them a very attractive policy tool."[190] The problem however occurs when discussing the role regulation really plays and whose interests it promotes.[191] Some scholars stand by the proposition that "interests promoted by regulatory agencies are frequently those of customer groups rather than those of the regulated firms themselves."[192] Other scholars on the other hand postulate that regulators create favorable law for the industry, as "given limited resources, regulators are dependent on the industries they regulate for cooperation and information."[193]

The answer might not however be one of a rational nature and an explanation may also lay partly in behavioral law and economics.[194] Behavioral law and economics were mentioned when discussing the Coase theorem. An important term was the so called *endowment effect* – the idea "that people often demand more to give up a good than to purchase it."[195] To recap, the importance of the endowment effect is that:

> The endowment effect challenges the fundamental assumption of economics that, absent wealth effects, an individual's maximum willingness to pay for a good should equal his minimum sale price. This assumption is at the heart of the conclusion that in markets with de minimis transactions costs, commodities will flow to the people who value them most.[196]

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[186] *See id.*
[187] *Id.* (*quoting* DANIEL A. FARBER & PHILIP P. FRICKEY, LAW AND PUBLIC CHOICE: A CRITICAL INTRODUCTION 44 (1991)).
[188] *See id.* at 1064.
[189] *Id.*
[190] *Id.* at 1065.
[191] *See id.* at 1070-1071.
[192] *Id.* at 1070 (*quoting* Richard A. Posner, *Theories of Economic Regulation*, 5 Bell J. Ec. & Mgmt. Sci. 335, 342 (1974)).
[193] *Id.* at 1072 (*quoting* Richard B. Stewart, *The Reformation of American Administrative Law*, 88 Harv. L. Rev. 1669, 1685-86 (1975)).
[194] *See id.* at 1089-1092.
[195] *Id.* at 1089.
[196] *Id.* at 1090 (*quoting* Jennifer Arlen, *Comment, The Future of Behavioral Economic Analysis of Law*, 51 Vand. L. Rev. 1765, 1771 (1998)).

The same rules apply in the corporate context.[197] The ambitions of many CEOs to build empires may not necessarily contribute to the postulate that resources flow towards those who value them the most.[198] Therefore, simple psychological mechanisms may serve as an explanation for the tragedy of the anticommons.

The roots of the tragedy however are not as important for legal scholars and scientists as its ramifications. The implications that are of greatest relevance here are those that concern biotechnological patents. As far as these consequences are concerned, two scenarios in which "patents unduly increase the transaction costs of research and development"[199] are named. The first scenario predicts that "numerous overlapping patents owned by different entities places a prohibitive burden on a scientist or company to negotiate licenses to thickets of patented technologies."[200] Thus, through the creation of too many concurrent fragments of intellectual property in potential future products, an anticommons is developed.[201] What said encompasses is the formation of a patent thicket "in which many independent patent holders have rights that cover a technology …."[202] This means that multiple, fragmented, and concurrent rights are created on potential future products.[203] The said scenario creates the necessity for those who wish to make a profit on the end-product, to obtain licenses from the owners of all the fragments of rights.[204]

The second scenario states that by permitting too many owners of upstream patents to stack licenses on top of the future discoveries of downstream users, an anticommons is born.[205] The patents may thus "act like tollbooths on the road to product

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197 *See id.*
198 *Id.*
199 Heller & Eisenberg, *supra* note 65, at 699; *see also* David E. Adelman, *Reassessing the Anticommons Debate in Light of Biotechnology Patent* Trends, *in 2* INTELLECTUAL PROPERTY AND INFORMATION WEALTH: ISSUES AND PRACTICES IN THE DIGITAL AGE, PATENTS AND TRADE SECRETS 301, 302-303 (Peter K. Yu ed., 2006).
200 Adelman, *supra* note 199, at 302-303.
201 Heller & Eisenberg, *supra* note 65, at 699.
202 Richard J. Gilbert, *Ties That Bind: Policies to Promote (Good) Patent Pools*, 77 Antitrust L.J. 1, 2 (2010).
203 Heather Hamme Ramirez, *Defending the Privatization of Research Tools: An Examination of the "Tragedy of the Anticommons" in* BIOTECHNOLOGY RESEARCH AND DEVELOPMENT, 59 Emmory L.J. 359, 368-369 (2004); *see also* Mireles, *supra* note 65, at 288 ("[C]oncurrent fragments of intellectual property rights may be granted in an end-product."); Gilbert, *supra* note 202, at 2 ("A patent thicket exists when rights to many patents from different patentees are necessary to lawfully make or sell a product (overlapping rights).").
204 Ramirez, *supra* note 203, at 369 ("[A] commercial end-product may require the use of multiple gene fragments, yet different owners may hold the rights to the individual fragments. A company that seeks to commercialize the end-product will need to obtain licenses from multiple owners before proceeding with product development.").
205 Heller & Eisenberg, *supra* note 65, at 699

development, adding to the costs and slowing the pace of downstream biomedical innovation."[206] The additional costs may be bread by reach-through licenses (RTLAs), which would force the developer to a situation where she would have to bargain with all the holders of the rights.[207] Although RTLAs "give the owner of a patented invention … rights in subsequent downstream discoveries", benefitting both the upstream patent holders and the downstream developers, if stacked, RTLAs may create a tragedy of the anticommons.[208] For this reason patent offices adopt various limitations on RTLAs.[209] In order to clarify further: the scenario of anticommons forming due to RTLAs presents as follows:

> A difficulty with licensing an upstream product or service is valuation .... Thus, a licensor may require that the license fee include a royalty base on a percentage of the sale price of a commercial end-product that was developed using the input .... The royalty amount is determined by reaching through to the sale of the commercial end-product. If numerous upstream inputs are necessary to develop a commercial end-product, the each owner of the patented input may request a reach-through royalty. The stacking of these royalty provisions may serve to provide a disincentive to develop a product that needs numerous inputs subject to such provisions because it erodes the profitability of the end-product.[210]

Both scenarios create the danger of holdouts.[211] A sad example of this is the story of a potential cure for Alzheimer's raised by Michael Heller.[212] For the compound to be developed numerous license agreements from numerous sources needed to be obtained.[213] Because the holders of the patents pursued their reasonable interests so fervently, the price for bundling all the licenses exceeded the expected profits for the drug.[214] The work was eventually put to a grinding halt, and the science behind the potential drug was kept confidential.[215]

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[206] *Id.*; *see also* Adelman, *supra* note 199, at 303.
[207] Ramirez, *supra* note 203, at 369 ("Reach-through provisions could lead to stacking licenses, and a potential developer would have to bargain with all of the rights holders before developing an end-product.").
[208] HELLER, *supra* note 120, at 62.
[209] *Id.* at 62-63.
[210] Mireles, *supra* note 65, at 288.
[211] Ramirez, *supra* note 203, at 370.
[212] *See* HELLER, *supra* note 120, at 4-6.
[213] *Id.* at 5.
[214] *Id.*
[215] *Id.* at 5-6.

At this juncture it is worth to mention a third factor, which may have emerged from the *Stanford v. Roche*[216] decision. This third factor is also a consequence of how rights to an invention are divided, or to be more precise – how this division may contribute to a prohibitive increase in costs.[217] The problem was underlined in Justice Breyer's and Ginsburg's dissenting opinion and relates to the interpretation of the Bayh-Dole Act[218]. The Act itself as well as the case will be described in more detail later. However, it is worth mentioning here that a new face of the tragedy of the anticommons may have emerged and it is related to a more legal issue. This will become more clear when discussing the mentioned case.

[216] *Bd. of Trustees of Leland Stanford Junior Univ.* v. *Roche Molecular Sys.*, Inc., 563 U.S. ___ (2011) (Breyer J., Ginsburg J. dissenting).
[217] And the costs of investigations into patent ownership are already high. *See* HELLER, *supra* note 120, at 66.
[218] Patent and Trademark Law Amendments Act (Bayh–Dole Act), 35 U.S.C. § 200-212 (2006) [hereinafter Bayh-Dole].

IV. THE TRAGEDY OF THE ANTICOMMONS IN THE PRACTICE OF BIOTECHNOLOGY

It seems truistic to say that biotechnology has changed a lot since the 1970s; this is however an important statement and a good beginning for an analysis of the tragedy of the anticommons. This is due to the fact that until the 1970s, the field of biotechnology resembled more of a commons model and the dissemination of information was conducted freely.[219] The dissemination was also governmentally encouraged to be made in an immediate fashion.[220] Few patents owned by the U.S. federal government were licensed, and the technology covered by those patents was not commercialized.[221] The free flow of information included the use of genetic material.[222] An example of the effectiveness of this system is the discovery of the monoclonal antibody.[223] Nevertheless, this system was considered by some to be too ineffective.[224] It was thus changed through the enactment of the Bayh-Dole Act in the 1980s.[225] Researchers began to increasingly patent their findings and via license agreements disseminate the new technologies with the aim of increasing revenues.[226] Large funds were also poured into the

[219] HELLER, *supra* note 120, at 58 ("Until the 1970s, much biomedical research followed a 'commons' model, under which anyone could use re-search results freely"); *see also*, Ramirez, *supra* note 203, at 365 ("Prior to 1980, scientific knowledge was generally viewed as a shared resource …[S]cientists exchanged research materials and information relatively freely and shared information without the use of formal agreements"); *see also* Heller & Eisenberg, *supra* note 65, at 698 ("[B]iomedical research has been moving from a commons model toward a privatization model.").
[220] Mireles, *supra* note 65, at 294; Heller & Eisenberg, *supra* note 65, at 698 ("Under the commons model, the federal government sponsored premarket or 'upstream' research and encouraged broad dissemination of results in the public domain.").
[221] Mireles, *supra* note 65, at 287.
[222] Sabrina Safrin, *Hyperownership in a Time of Biotechnological Promise: The International Conflict to Control the Building Blocks of Life*, 98 Am. J. Int'l L. 641, 644 (2004).
[223] HELLER, *supra* note 120, at 58.
[224] Mireles, *supra* note 65, at 287 (*noting* Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 Va. L. Rev. 1663, 1702 (1996)) ("Proponents of the act believed that the government was not effective in tranferring patents to private industry for commercialization and that allowing funding recipients to take title to inventions developed with government funding would provide the necessary incentive to private industry to commericialize those inventions.").
[225] Ramirez, *supra* note 203, at 365.
[226] *Id.* at 365 ("[A]fter the enactment of the Bayh-Dole Act, many researchers and institutions that received federal grants sought to obtain patent protection on new discoveries in order to increase revenues from licensing."); Mireles, *supra* note 65, at 284, 287 ("The increased licensing, patenting and startupt activity since the passage of the Bayh-Dole Act is substantial."); *see also* Heller & Eisenberg, *supra* note 65, at 698 ("In 1980, in an effort to promote commercial development of new technologies, Congress began encouraging universities and other institutions to patent discoveries arising from federally supported research and development and to transfer their technology to the private sector.").

biotech industry.[227] This is where the beginning of the tragedy of the anticommons may be found, and this is where "[t]he traditional paradigm that genetic resources formed part of a global commons was eroded by the extension of patents to living organisms and later to genetic material."[228] It would therefore be prudent at the beginning of this chapter to explore the basics of what and how the Bayh-Dole Act brought.

The reason why the U.S. Congress enacted the mentioned piece of legislation was "to move the results of government-funded research that was not being used to the marketplace for the benefit of the investors in that research – the taxpayer"[229] The reasons for the act are in essence expressed in the act itself:

> It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise without unduly encumbering future research and discovery; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.[230]

Thus, the said piece of legislation showed a shift of federal policy from a public-domain-orientation to a pro-patent one.[231] The Bayh-Dole Act put the accent on the private industry to undertake great costs of research in exchange for a reward of exclusive rights in the form of a patent.[232] What in essence the act does is enable the private industry to collaborate financially with research institutions (especially universities). It did so by encouraging universities to patent, take a proprietary interest in,[233] their findings, which arose from federally funded research, and later commercialize the said discoveries.[234] The proprietary interest, or simply privatization, in this context "takes the

[227] HELLER, supra note 120, at 5, 58.
[228] Safrin, *supra* note 222, at 645.
[229] Mireles, *supra* note 65, at 283.
[230] Bayh-Dole, *supra* note 218, § 200.
[231] Ramirez, *supra* note 203, at 365..
[232] *See id.* at 365 ("Bayh-Dole … stressed the need for exclusive rights as an incentive for industry to undertake the costly investment necessary to bring new products to market.").
[233] Mireles, *supra* note 65, at 284.
[234] HELLER, *supra* note 120, at 58.

form of intellectual property claims to the sorts of research results that, in an earlier era, would have been made freely available in the public domain."[235] The act achieves this goal by allocating rights in federally funded inventions[236] between the Federal Government and federal contractors:

> Each nonprofit organization or small business firm may, within a reasonable time after disclosure…, elect to retain title to any subject invention.[237]

As a result, the National Institutes of Health (NIH), and many universities created their own technology transfer offices,[238] which have considerably decreased the transaction costs of transferring patent rights.[239] Hence, upstream research in the biomedical industry began to be dominated by private institutions.[240] The result of the shifting of costs enabled great medical advances, examples being: MRI body scanning technology, the vaccine for hepatitis B, the atomic-force microscope, even the technology of Google's research engine.[241]

Despite the advantages, ample criticism has been targeted towards the Bayh-Dole Act.[242] More and more voices started to sound the alarm that the act may have brought unintended consequences, which may prove hurtful to research.[243] The most notable criticism is of course that "[p]rivatization of upstream biomedical research … may create anticommons property."[244] Furthermore, a lion's share of the research is conducted by university spin-offs.[245] The private funds that flow into these entities often enable private companies to control the research.[246] An article in *The Economist* describes the attitude of scientists, in whose opinion "the act distorts the mission of uni-

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235 Heller & Eisenberg, *supra* note 65, at 698.
236 Bayh-Dole, *supra* note 218, § 201 ("The term 'subject invention' means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement…").
237 *Id.* § 202(a).
238 Mireles, *supra* note 65, at 284; Heller & Eisenberg, *supra* note 65, at 698.
239 *Cf.* Mireles, *supra* note 65, at 288 ("[O]wners of upstream inputs include universities and other public entities that are not used to fast-paced market bargaining and have limited resources. The longer the Bayh-Dole Act remains in effect, the less likely this will be a problem.").
240 Heller & Eisenberg, *supra* note 65, at 698.
241 *Bayhing for blood or Doling out cash?*, THE ECONOMIST, December 20, 2005, *available at* http://www.economist.com/node/5327661/print (last visited 2 August 2011).
242 *See id.*; *see also* Mireles, *supra* note 65.
243 *See* HELLER, *supra* note 120; *see also Bayhing for blood or Doling out cash?*, *supra* note 241.
244 Heller & Eisenberg, *supra* note 65, at 698.
245 Li, *supra* note 48, at 349.
246 *Accord* HELLER, *supra* note 120, at 57; *Bayhing for blood or Doling out cash?*, *supra* note 241.

versities, diverting them from the pursuit of basic knowledge, which is freely disseminated, to a focused search for results that have practical and industrial purposes."[247]

From a more economic standpoint the Bayh-Dole Act also contributed to an increase in transaction costs as far as the transferring of rights are concerned, despite the creation of technology transfer offices.[248] A major factor for the high transaction costs is the heterogeneity of interests, which may prevent the transfer of rights.[249] The mentioned "focused search for results that have practical and industrial purposes"[250] in research was contributed to the competitive environment, which the Act brought.[251] For this reason, no standard licensing scheme emerged, and thus private entities were forced to conduct case-by-case negotiations.[252] Moreover, public entities are more willing to disseminate the results of their research as fast as possible, while it is in the better interest of private entities to delay publication in order to gain a market advantage.[253]

The new possibilities, which this piece of legislation brought, gave birth to new phenomena. One was defensive patenting, compared to the Cold War mutually assured destruction strategy (MAD).[254] This behavior is aimed at obtaining such a patent, which would force others to cross-license.[255] Another phenomenon was the emergence of *patent trolls*.[256] These are specialized firms, which do not invent but "seek out and buy control of relatively low-value, weak patents that may be infringed in the course of creating more valuable products."[257] Patent trolls make money through litigation or settlements.[258] Due to the aforementioned, the costs of research and development (R&D) rose substantially, as illustrated below.[259]

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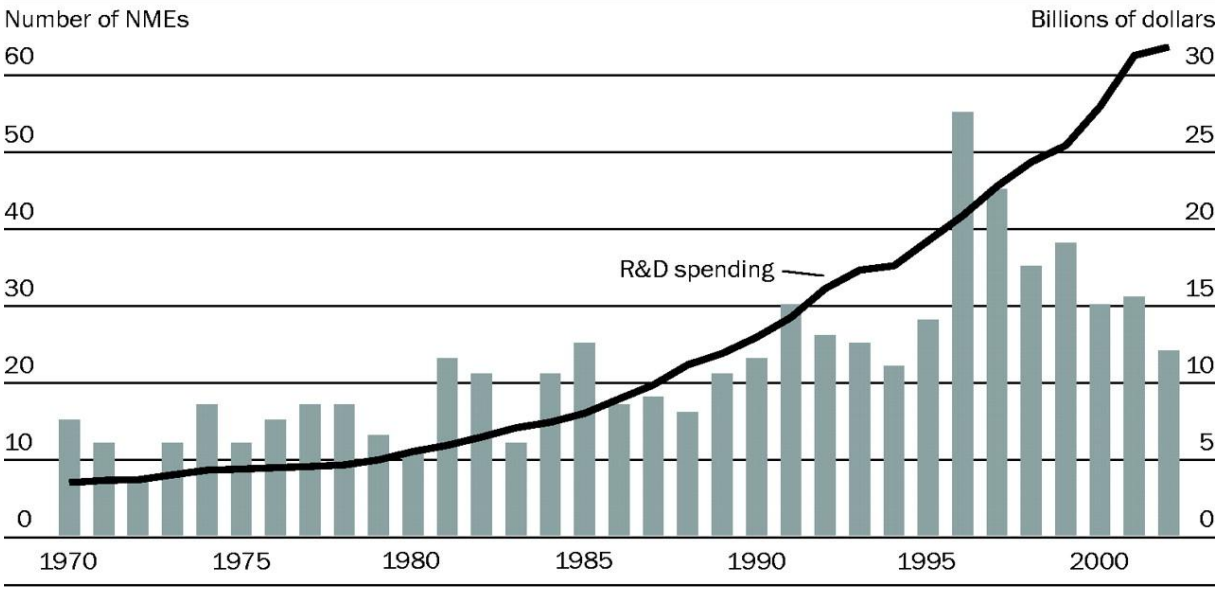
[247] *Bayhing for blood or Doling out cash?*, *supra* note 241; *accord* Mireles, *supra* note 65, at 293; LANDES & POSNER supra note 40, at 316; *see also* Heller & Eisenberg, *supra* note 65, at 698 ("[C]ritics fear deterioration in the culture of upstream research.").
[248] *See* Mireles, *supra* note 65, at 288-289.
[249] *Id.* at 289.
[250] *Bayhing for blood or Doling out cash?*, *supra* note 241.
[251] *See* HELLER, *supra* note 120, at 58.
[252] Mireles, *supra* note 65, at 289.
[253] *Id.* at 289.
[254] HELLER, *supra* note 120, at 58-59.
[255] See *id.* at 59 ("This strategy of defensive patenting is also sometimes referred to by the cold war label 'mutual assured destruction,' or MAD. For equally balanced competitors, a MAD strategy may lead to détente – firms cross-license their patents and forgo litigating.").
[256] *See id.*; *see also* Don Clark & Dionne Searcey, *Big Patent Firm Sues Nine Tech Firms*, THE WALL STREET JOURNAL, December 9, 2010.
[257] HELLER, *supra* note 120, at 59.
[258] *Id.*
[259] *Id.*

EXHIBIT 1
Pharmaceutical Research And Development Trends In The United States, 1970–2002



SOURCES: For number of new molecular entities (NMEs) approved, U.S. Food and Drug Administration, Center for Drug Evaluation and Research. For PhRMA members' spending, Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile, 2002* (Washington: PhRMA, 2003).
NOTE: Line relates to the right *y* axis and denotes worldwide research and development (R&D) spending by PhRMA member companies, inflation-adjusted to constant 2002 dollars by the National Institutes of Health (NIH) Biomedical R&D price deflator.

THE RISE OF R&D IN THE U.S. [260]

The graph shows that research and development spending is on the rise.[261] However, the development of new drugs does not rise in accordance with the rise of that spending.[262] This "fewer bangs for more bucks"[263] phenomenon is, with a degree of carefulness, attributed to the tragedy of the anticommons.[264]

As highlighted previously, there may also exist an additional factor that may contribute to yet higher transaction costs, ones related to uncertainty as to whom the patent holder is or will be. To get a full picture of the issue, it is crucial to present the facts and the legal question of *Stanford v. Roche*[265].

In 1985, Cetus, a California company, began the development of methods for quantifying blood-borne levels of the human immunodeficiency virus (HIV).[266] Three years later the company began collaborating with Stanford University on the develop-

[260] *Exhibit from*: Iain M. Cockburn, Health Affairs, *The Changing Structure Of The Pharmaceutical Industry*, 1 Health Affairs 10, *available at* http://content.healthaffairs.org/content/23/1/10/F1.large.jpg
[261] HELLER, *supra* note 120, at 59.
[262] *Id.* at 60.
[263] *Id.*
[264] *Id.*
[265] *Bd. of Trustees of Leland Stanford Junior Univ.* v. *Roche Molecular Sys.*, Inc., 563 U.S. ___ (2011).
[266] *Id.* at 1.

ment of new AIDS drugs.[267] One of the scientists who joined the Stanford research team, Dr. Mark Holodniy, signed a Copyright Patent Agreement, in which he agreed to assign all his rights in a future invention to the University.[268] Part of his research however was also conducted at Cetus, which required him to sign a Visitor's Confidentiality Agreement.[269] The agreement provided for a similar provision as the Stanford Copyright Patent Agreement.[270] Whilst working with Cetus employees, Holodniy devised a procedure for calculating the amount of HIV in a patient's blood.[271] The assets related to the discovery were later acquired by Roche, which commercialized it, based on the Visitor's Confidentiality Agreement, signed by Holodniy.[272] Subsequently a dispute over who has the patent rights to the discovery – Stanford University or Roche – arose.[273]

In its analysis, the U.S. Supreme Court dissected two provisions of the Bayh-Dole Act. The first was the definition of "subject invention" of §201(e) stating that it is: "any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement."[274] The second was §202(a) declaring that: "Each nonprofit organization or small business firm may, within a reasonable time after disclosure…, elect to retain title to any subject invention…."[275] Stanford University and the U.S. government argued that since the research was federally funded, then the contractor, i.e. the University, is the holder of the patent.[276] The backbone of this argument was that "Holodniy had no rights to assign because the University's HIV research was federally funded, giving the school superior rights in the invention under the Bayh-Dole Act."[277] The Supreme Court disagreed with this assertion, as The Bayh-Dole Act does not automatically vest title to federally funded inventions in federal contractors or authorize contractors to unilaterally take title to such inventions.[278] For such an assignment to take place, there needs to be an agreement to that effect.[279] The Bayh-Dole Act

[267] *Id.* at 1-2.
[268] *Id.* at 2.
[269] *Id.*
[270] *Id.*
[271] *Id.*
[272] *Id.* at 2-3.
[273] *Id.* at 4.
[274] Bayh-Dole, *supra* note 218, § 201(e).
[275] *Id.* § 202(a).
[276] *Stanford v. Roche*, 563 U.S. at 4.
[277] *Id.* at 4-5.
[278] *Id.* at 8, 10-11.
[279] *Id.* at 7.

does not provide for this vesting, unless the invention is a "subject invention"[280] under the Act.[281] But since the employment contract was not such an express agreement, then Holodniy's discovery was subject to the Visitor's Confidentiality Agreement.[282] The reason for this is the fundamental rule of patent law that inventors have the right to their inventions,[283] a rule expressed in the Patent Act[284]:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter … may obtain a patent therefor.[285]

Further, the Supreme Court argued, there is nothing in the Bayh-Dole Act, which strays from the mentioned rule, as "[i]t would be noteworthy enough for Congress to supplant one of the fundamental precepts of patent law and deprive inventors of rights in their own inventions. To do so under such unusual terms would be truly surprising."[286] Interestingly enough, this conclusion goes against the warnings raised by Michael Heller who stated that "[u]pstream patent rights, initially offered to help attract further private investment, are increasingly regarded as entitlements by those who do research with public funds."[287] On the other hand, the ruling of the court still falls in line with the subsequent part of Heller's article: "A researcher may have felt entitled to coauthorship or a citation in an earlier era may now feel entitled to be a coinventor on a patent or to receive a royalty under a material transfer agreement."[288]

Most relevant to the topic at hand however was the dissent. Justice Breyer, indirectly, raised the issue of the tragedy of the anticommons, by underlining the deterrence of innovation due to patent law.[289] But he seems to show new reasons for which the tragedy of the anticommons may emerge, reasons stemming from the Supreme Court's decision. The interpretation of the Bayh-Dole accepted by the majority of the Justices breeds certain negative consequences:

> It allows individual inventors, for whose invention the public has paid, to avoid the Act's corresponding restrictions and conditions. And it makes the commercialization and marketing of such an invention more difficult:

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[280] Bayh-Dole, *supra* note 218, §202(a).
[281] *Stanford v. Roche*, 563 U.S. at 13-14.
[282] *Id.* at 5.
[283] *Id.* at 6-7.
[284] Patent Act, 35 U.S.C. §§ 1-376 (2006) [hereinafter Patent Act].
[285] *Id.* §101.
[286] *Stanford v. Roche*, 563 U.S. at 14.
[287] Heller & Eisenberg, *supra* note 65, at 698.
[288] *Id.*
[289] *Stanford v. Roche*, 563 U.S. at 2 (Breyer J., Ginsburg J. dissenting).

> A potential purchaser of rights from the contractor, say a university, will not know if the university itself possesses the patent right in question or whether, as here, the individual, inadvertently or deliberately, has previously assigned the title to a third party.[290]

For this reason, Justice Breyer mentions the importance of the goals of the Bayh-Dole Act, which should, in his opinion serve, as the countervailing considerations for the traditional norms of patent law.[291]

The Bayh-Dole Act however is not the beginning or the end of the problem. The tragedy of the anticommons seems not to be limited only to the U.S. Its international consequences are being made heard more often. For example, the president of Tanzania expressed his concerns over the asymmetry of patenting in the following words:

> The trend of genetically rich countries, however, has been the opposite: to restrict and encumber access to raw genetic material within their borders, largely in response to the increased patenting of genetic material and bioengineered goods since the conclusion of the CBD. These countries particularly object to developed countries' granting of patents to genes isolated from material that was taken from or originated in developing countries. They view such patenting as colonial-style taking or theft.[292]

This is also an important quote in the debate over gene patenting, which will be discussed later. What must be highlighted at this juncture, is that the debate over the tragedy of the anticommons, becomes more factually-based and policy-oriented. And there is indeed a plethora of facts, which may be interpreted in various ways. Certain actions by big business breed fertile ground to speculate on whether the tragedy of the anticommons has shown itself. One of the most important reactions to allegedly anticommons property was a redirection of investment, and the abandonment of certain fields.[293] This is the issue with such companies as IBM (donation of five hundred software-code patents to the public), Celera (donation of its DNA database to the public), or Bristol-Myers Squibb (abandonment of the investigation of 50 proteins due to the high costs of royalties).[294]

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[290] *Id.* at 5.
[291] *Id.* at 6.
[292] Safrin, *supra* note 222, at 647.
[293] HELLER, *supra* note 120, at 2.
[294] *Id.*

The already mentioned Alzheimer's drug example,[295] suggests that all of these actions are due to the increasing costs of research and development, which are a result of the proliferation of patents, especially weak ones.[296] Other examples are also mentioned. A notable example is the research behind a cure for severe acute respiratory syndrome (SARS).[297] Although the research was conducted in an amicable atmosphere, the later controversy that emerged was patent-related.[298] Seeing the potential legal threat, the World Health Organization issued the following statement:

> In the longer terms, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases.[299]

Another example, one with a happy ending however, concerns the development of so called golden rice.[300] This biotechnological invention was aimed at modifying rice in such a way, so as to decrease vitamin A deficiency, which was a substantial cause of children's blindness.[301] Developed in 1999, the golden rice was vitamin-A-enhanced.[302] In order to be exploited however, licenses for over seventy patents had to be achieved.[303] Sufficed to say, the expenses were enormous.[304] Quite obviously the scientists were unable to achieve all the agreements on their own.[305] Thanks to a company, Zeneca (today Syngenta), the introduction of the crops to the market was thankfully possible.[306] According to Michael Heller this is a warning about the possible future:

> Inspired leadership makes a difference, and shame can be a potent tool for forging agreement. Reputation matters: firms like to advertise their involvement in successful humanitarian ventures …. When the stakes are higher, then cooperation often fails and easy solutions give way.[307]

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295 *Id.* at 4-6.
296 *Id.* at 53.
297 See *id.* at 54-55.
298 *Id.* at 54. However, the SARS efforts resulted in the creation of a patent pool. Patent pools will be discussed later. *See* Patrick Gaulé, *Towards Patent Pools in Biotechnology?*, CEMI-REPORT-2006-010, April 2006, at 3.
299 HELLER, *supra* note 120, at 54.
300 *See id.* at 55-56.
301 *Id.* at 55.
302 *Id.*
303 *Id.*
304 *Id.*
305 *Id.* at 56.
306 *Id.*.
307 *Id.* at 56-57.

This warning is especially potent when one analyzes the patenting of research tools. Research tools are referred to as *upstream* products, due to the fact that they are used at the early stage of development of end-products.[308] It has been argued that their privatization has led to the deterrence of research.[309] A notable example are expressed sequence tags (ESTs), which "are usually 200 to 500 nucleotides long, and are generated by sequencing either one or both ends of an expressed gene. An EST can be used to identify an expressed gene and can also be used as a sequence-tagged site marker to locate a particular gene on a physical map of a genome."[310] They are in essence tools used to find certain parts of DNA.[311] An initial boom in the patent applications for ESTs has in some opinions contributed to a hurtful waive of defensive patenting.[312] However, in the case of research tools the problem is not as simple as it may seem. Namely, it is not always easy to state what a research tool is, as it depends on the perspective.[313] "[S]omething could be used as both a research tool and an end-product."[314] The prime examples are cell receptors, which may be used as pharmaceuticals, i.e. end-products, or research tools, such as screening assays in the process of hormone detection.[315] Due to this relativity, the NIH issued recommendations as to what to classify as a research tool, these included:

1) the primary usefulness of the resource is as a tool for discovery rather than an FDA-approved product or integral component of such a product;
2) the resource is a broad, enabling invention that will be useful to many scientists . . . rather than a project or product-specific resource; and
3) the resource is readily useable or distributable as a tool rather than the situation where private sector involvement is necessary or the most expedient means for developing or distributing the resource.[316]

The research tools example is the topic of heated debates, as it is also raised that the biotech industry has in actuality benefitted from the privatization of research

[308] Ramirez, *supra* note 203, at 360.
[309] *See* Heller & Eisenberg, *supra* note 65, at 698. *Contra id.* at 381.
[310] Cynthia D. Lopez-Beverage, *Should Congress do Something About Upstream Clogging Caused by the Deficient Utility of Expressed Sequence Tag Patents?*, 10 J.Tech.L.& Pol'y 35, 47-48 (2005); *see also* MICHAŁ DU VALL, PRAWO PATENTOWE 365 (Joanna Fitt ed., Wolters Kluwer Polska 2008).
[311] Lopez-Beverage, *supra* note 310, at 48
[312] HELLER, *supra* note 120, at 58-61
[313] Ramirez, *supra* note 203, at 366
[314] *Id.*
[315] *Id.*
[316] *Id.* at 366-367 (*quoting* Principles and Guidelines, 64 Fed. Reg. 72,090, 72,094 (Dec. 23, 1999)).

tools.[317] Before however an analysis of the biotech industry can commence a brief summary of patent law in the U.S. and the E.U. is crucial.

1. PATENT LAW IN THE UNITED STATES AND THE EUROPEAN UNION

Most research in the topic of the tragedy of the anticommons is from the U.S. It is therefore unsurprising that the legal analysis on the subject touches upon U.S. law. After all, the Bayh-Dole Act, which sparked the anticommons debate is an American normative act. But also European law is mentioned quite often in the debate. A comparative approach is not the goal of this thesis. However, it seems prudent to briefly analyze the two patent systems in the most general terms.

A major difference between the European and U.S. patent systems is the approach to the issue of morality.[318] For example, U.S. law does not ban the patenting of medical processes, such as gene therapy, while European law does.[319] The said difference is visible in the adoption of TRIPS Article 27(2) "order public and morality" exception.[320] Article 53 of the European Patent Convention (EPC), as well as Article 6 of the Biotechnology Directive[321] apply this exception.[322] The latter states:

> Article 6
> 1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality.[323]

The topic of what exactly a biotechnological invention is will be discussed later. Sufficed to say at this juncture is that what constitutes a biotechnological invention as far as genes are concerned is their removal, isolation, and identification of a useful func-

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317 *See id.* at 373.
318 *See* Li, *supra* note 48, at 353.
319 Convention on the Grant of European Patents (European Patent Convention), art. 52(4), Oct. 5, 1973,
1065 U.N.T.S. 19 [hereinafter EPC]; *id.* at 352.
320 TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 27(2), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS] ("Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law."); *see also* Li, *supra* note 48, at 353.
321 Parliament and Council Directive 98/44, 1998 O.J. (L 213) (EC) [hereinafter Biotech Directive].
322 Li, *supra* note 48, at 353.
323 Biotech Directive, art. 6.

tion.[324] And naturally, one who obtains a patent for such an isolated and purified gene, the holder of the patent, is able to prevent others from making or using the said gene.[325]

The notable beginning of biotechnological patents in the U.S. is the *Diamond v. Chakrabaty*[326] decision. In the mentioned case the plaintiff sough a patent for a bacterium that was able to clean oil spills over water.[327] The question was whether this was patentable subject matter within the meaning of the Patent Act:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.[328]

The court accepted the patentability of the bacterium, as "respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter-a product of human ingenuity "having a distinctive name, character [and] use."[329] To this day the Supreme Court's cite to a congressional hearing, often erroneously attributed to the Supreme Court itself, is famous that patent subject matter is to "include anything under the sun that is made by man."[330] The barrier of what is considered to be patentable subject matter was further moved by Harvard University's patenting of the *OncoMouse* – a genetically engineered mouse susceptible to cancer.[331] However, what should be mentioned when discussing the OncoMouse is that not all jurisdictions are in agreement as to its patentability, as the Canadian Supreme Court rejected the OncoMouse patent on the basis that it was a "higher life form."[332]

As discussed above, the Bayh-Dole Act has become a very important part of U.S. law concerning patents. The most recent development in that regard has been the

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[324] Safrin, *supra* note 222, at 645 ("A patent, however, can be obtained when that gene has been removed and isolated, and a useful function for it identified.").
[325] *Id.* at 646.
[326] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
[327] *Id.* at 305; a*ccord* Anuranjan Sethi, *Patenting Genes: Understanding Legal and Policy Implications*, *available at* http://www.intelproplaw.com/Articles/files/Patentinggenes.pdf; DU VALL, *supra* note 310, at 363.
[328] Patent Act, *supra* note 284, § 101.
[329] *Diamond v. Chakrabarty*, 447 U.S. 303, 309-310 (1980).
[330] *Id.* at 309 (*quoting* S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No.1923, 82d Cong., 2d Sess., 6 (1952))
[331] *Accord* DU VALL, *supra* note 310, at 363; Sethi, *supra* note 327.
[332] Gary Stix, *Owning the Stuff of Life*, 294 SCI. AM., 76, 82-83 (2006).

case of *Stanford v. Roche* where the Supreme Court reinforced the rights of the inventor to her invention.[333] Thus, there is no need to discuss this case and the act once again.

2. BIOTECHNOLOGICAL INVENTIONS IN GENERAL

Article 27 of TRIPS defines what is patentable subject matter. The first part of this article states:

> Article 27
>
> 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.[334]

What Article 27 does not states however is what an *invention* is, this includes a biotechnological invention.[335] The European Union's reply to this lack of a definition was the so called Biotechnology Directive, which tries to define the term in the following provisions:

> Article 3
>
> 2. Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature.[336]

Biological material on the other hand is defined in Article 2(1)(a) as being "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system."[337]

The European Biotechnology Directive allows for this under certain conditions. These were already mentioned earlier.[338] As far as human genes are concerned however, an additional limitation comes into play:

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[333] *Bd. of Trustees of Leland Stanford Junior Univ.* v. *Roche Molecular Sys.*, Inc., 563 U.S. ___ (2011).
[334] TRIPS, *supra* note 320, art. 27(1).
[335] Li, *supra* note 48, at 350.
[336] Biotech Directive, *supra* note 321, art. 3.
[337] *Id.* art. 2.
[338] *Id.* art. 3(2) ("Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature."), art. 2(1)(a) ("'biological material` means any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.").

Article 5

1. The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
2. An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.

Also the law of the United States reached a similar conclusion.[339] In *Amgen, Inc. v. Chugai Pharmaceutical Co.*[340], the U.S. Court of Appeals for the Federal Circuit concluded that "human DNA sequences, even if they exist naturally in the human chromosome, are patentable as long as they are 'purified and isolated' from the original object in nature."[341]

Human DNA sequences are however patentable under the condition that "they are isolated and purified, as long as the sequence can be accurately expressed and has an industrial application."[342] There is quite obviously a common theme prevailing throughout the different laws, which is isolation or purification. This topic will be developed further in the subsequent chapter. For now, it seems prudent to analyze the common points as far as patent requirements are concerned between the U.S. and European systems.

The first requirement is novelty. Some opponents of DNA patenting raise that this requirement is not fulfilled, as it already exists in nature.[343] However, in light of the mentioned requirement of isolation or purification, this seems to be an erroneously construed argument. Its *better* version will be discussed later. The novelty of biological material is composed of two points. The first, is the information about the material; the

339 Li, *supra* note 48, at 351.
340 *See Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200 (Fed. Cir. 1991).
341 Li, *supra* note 48, at 351. A similar example can be drawn from China's Patent Law, which prohibits the granting of patents for mere scientific discoveries. Article 25 of China's Patent Law states:
For any of the following, no patent right shall be granted:
(1) scientific discoveries;
(2) rules and methods for mental activities;
(3) methods for the diagnosis or for the treatment of diseases;
(4) animal and plant varieties;
(5) substances obtained by means of nuclear transformation.
For processes used in producing products referred to in items (4) of the preceding paragraph, patent right may be granted in accordance with the provisions of this Law.
342 Li, *supra* note 48, at 351.
343 *See* DU VALL, *supra* note 310, at 372.

second, the method of its isolation.[344] Thus novelty of biological material is identical to the novelty requirement concerning chemical substances.[345]

The second requirement is the nonobviousness requirement, referred to in Europe and most other countries as an inventive step.[346] In deciding whether an inventive step was taken, one compares "the differences between the subject matter sought to be patented and the prior art to see whether the subject matter as a whole would have been obvious to a person having ordinary skill in the art."[347] The issue of the nonbviousness requirement is one that gained significant importance in biotechnology for the reasons stated below.[348]

As far as DNA sequences are concerned, it is often raised that sequencing is a routine procedure, since the mere extraction of DNA from nature and the determination of its nucleotide sequence is obvious.[349] Hence, some scientists raise that "any monkey can generate numerous unidentified gene sequences."[350] For this reason, gene patenting has also been criticized on the base of the nonobviousness or inventive step requirement. However, the nucleotide sequence may not be obvious, and thus biological material will not be granted a patent, if it is determined to not fulfill the inventive step requirement.[351] Moreover, although the technique is routine, it costnly, time-consuming, and not easy.[352] The latter opinion however seems a bit strange, as patents are not granted because of sheer hard work, but for the contribution made for disclosing socially beneficial achievements.

An approach taken by U.S. courts to the nonobviousness requirement was the doctrine of structural similarity.[353] That meant viewing DNA as a chemical compound.[354] However, since this approach was hard to apply to DNA, early U.S. case law focused on the obviousness of the method.[355] In *In Re Deuel*,[356] took a different ap-

344 *Id.*
345 *Id.*
346 Li, *supra* note 48, at 355.
347 *Id.*
348 Lopez-Beverage, *supra* note 310, at 37.
349 DU VALL, *supra* note 310, at 373; Li, *supra* note 48, at 355.
350 Li, *supra* note 48, at 355.
351 DU VALL, *supra* note 310, at 373; Li, *supra* note 48, at 355 (*referring to* Kate H. Murashige, *Genome Research and Traditional Intellectual Propery Protection – A Bad Fit?*, 7 RISK: Health, Safety & Environment 231 (1996), *available at* http://www,piercelaw.edu/risk/vol7/summer/murashig.htm).
352 Li, *supra* note 48, at 355.
353 *Id.* at 356.
354 *Id.*
355 *Id* at 357.
356 *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995).

proach to the mentioned doctrine.[357] the Federal Circuit reasoned that "a prior art disclosing the amino acid sequence of a protein does not automatically make the particular DNA molecules encoding the protein obvious."[358] However, a DNA sequence would be considered obvious, if it would be structurally similar to another to another prior art chemical compound.[359]

Artcile 56 of the EPC describes the inventive step requirement in the following manner:

> An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.[360]

In applying this standard the European Patent Office (EPO) used a problem-solution approach, consisting of four steps.[361] The first step, was to focus on the nearest prior art to find the problem to be solved.[362] The second, to find a solution or technical teaching in the invention.[363] Third, to decide if the solution meets the problem in the prior art.[364] And finally, to decide whether a skilled person in the field would consider the solution as obvious.[365] Moreover, similarly to the U.S. case of *In re O'Farrell*,[366] the EPO applies the reasonable expectation of success approach.[367] The application of the abovementioned steps can be illustrated by the Relaxin/Howard Florey case:

Problem	"The problem to be solved can be defined as isolating and characterising a DNA encoding a further relaxin ….
Solution	The solution provided to that problem is the human DNA fragment encoding the H2-relaxin having the specific sequence ….
Meeting the problem in the prior art	[I]t may, then, have been common practice to isolate a DNA fragment from a given species by hybridisation of the cloned DNA to a probe consisting in the DNA encoding the same protein in another species ….
Would a skilled person in the filed consider the solution as obvious	[T]he skilled person would have had reasons to doubt that such an homology would exist between the human and rat or porcine relaxin DNAs ….

357 DU VALL, *supra* note 310, at 374.
358 Li, *supra* note 48, at 357.
359 DU VALL, *supra* note 310, at 374.
360 EPC, *supra* note 319, art. 56.
361 Li, *supra* note 48, at 358.
362 *Id.*
363 *Id.*
364 *Id.*
365 *Id.*
366 *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988).
367 Li, *supra* note 48, at 358.

Reasonable expectation of success.	Thus, there existed no reasonable expectation of success that the claimed human relaxin encoding DNA may be isolated. Inventive step is acknowledged."[368]

The final patent requirement is industrial application, referred to in the U.S. as the utility requirement.[369] Although the said requirement seemed obvious in the case of chemical substances, it became problematic as far as DNA is concerned.[370] A common problem of this requirement is knowledge concerning the application of the patented substance.[371] In the case of DNA it has been argued that scientists should know the exact function of a gene when wishing to patent it.[372] This was the case in the 1980s when "patents on genes generally corresponded closely to foreseeable commercial products, such as therapeutic proteins or diagnostic tests for recognized genetic diseases."[373] However, the NIH's application for a patent on ESTs created the problem of patenting anonymous gene fragments.[374] As one study indicated various problems arise in this regard:

> Some patents exhibited written description problems by claiming discoveries the patent holder did not specifically describe. One patent covers not only the particular polymorphism the inventor discovered but all other polymorphisms discovered in the future ….
> Other patent claims were problematic with respect to utility. In one patent, the inventor had shown how a polymorphism could be used to predict asthma. The inventor additionally claimed various uses of the polymorphism to predict other conditions, although the inventor did not show that the polymorphism was linked to those conditions.[375]

Although the NIH changed its position and stopped filing for patents for ESTs, private entities were more than willing to take its place.[376] A common example of such problems is the patent for the CCR5 gene.[377] When the company, HGS, applied for a

[368] T 0272/95 [2002] E.P.O.R. 12 (Technical Bd. App. 1995) [hereinafter Florey/Relaxin]
[369] DU VALL, *supra* note 310, at 374.
[370] *Id.* at 375.
[371] Li, *supra* note 48, at 359.
[372] *Id.* (*referring to* Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exception*, 76 N.Y.U. L. Rev. 1623, 1626 (2001)..
[373] Heller & Eisenberg, *supra* note 65, at 699.
[374] *Id.*
[375] Jordan Paradise et al., *Patents on Human Genes: An Analysis of Scope and Claims,* 307 SCI. 1566, 11 March 2005.
[376] Heller & Eisenberg, *supra* note 65, at 699.
[377] Li, *supra* note 48, at 359.

patent for the mentioned gene, it was not aware of the role it plays in the HIV virus.[378] Additionally it is raised that because 97 percent of three billion base pairs lack any function, while the remaining 3 percent's function is unknown, the genome lacks patentability for lack of utility.[379] Despite said problems, it is nevertheless raised that if the patent claims mention a function, e.g. the coding of a protein, then it cannot be stated that the utility requirement has not been fulfilled.[380]

U.S. jurisprudence in the *Brenner v. Manson*[381] case handled the utility requirement by creating the so called practical utility standard stating that "[a] specific benefit or function needs to be shown".[382] Although the CCR5 gene failed this standard, a patent has been granted.[383] The problem with the lack of specificity of the utility standard was addressed by the USPTO through the issuance of new guidelines in January 2001, describing a new and higher standard as: "specific and substantial utility that is credible."[384] The standard broadens the scope of the granted patent, by granting the patent for the gene, even if only one of its function was disclosed, and precluding others from patenting additional functions.[385] Furthermore, the USPTO establish certain steps, which must be taken to fulfill the utility test.[386] First, it needs to be well-established, which means that "a person skilled in the art can immediately appreciate why the gene is useful."[387] Second, the specific DNA target must be disclosed. Third, the patented DNA needs to be substantial, i.e. it has to have a real-world use, e.g. therapeutic method of treating a known disease.[388] Finally, it needs to be credible, meaning it has to be conceivable in accordance with the disclosure in the application.[389]

Concerning the industrial application requirement, Article 57 of the EPC states that "an invention shall be considered as susceptible of industrial application if it can be

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[378] *Id.*
[379] *Id.* at 348 (this is however only an additional requirement, since the genome lack patentability also for lack of novelty).
[380] *Cf.* DU VALL, *supra* note 310, at 375.
[381] *Brenner v. Manson*, 383 U.S. 519 (1966).
[382] Li, *supra* note 48, at 359; *see also* DU VALL, *supra* note 310, at 375.
[383] Li, *supra* note 48, at 359.
[384] *Id.* at 360 (*quoting* Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001) [hereafter USPTO Guidelines]); *see also* DU VALL, *supra* note 310, at 376; HELLER, *supra* note 120, at 61; Stix, *supra* note 332, at 81.
[385] Li, *supra* note 48, at 360 (*quoting* USPTO Guidelines, *supra* note 384, at, 1098 (stating that "a patent on a composition gives exclusive rights to the composition for a limited time, even if the inventor disclosed only a single use for the composition.")).
[386] *Id.* at 360 (*referring to* U.S. Patent & Trademark Off., Manual of Patent Examining Procedure § 2107 (8th ed. 2001).
[387] *Id.*; *see also* DU VALL, *supra* note 310, at 376.
[388] *Id.*
[389] *Id.*

made or used in any kind of industry, including agriculture."[390] Further, the EC Biotechnology Directive develops this term. First, in Article 5(3): "The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application."[391] And in Recital 24: "Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention …."[392] Thus what constitutes a biotechnological invention is the indication of its function.[393] Due to this, the EPO has applied a similar utility standard to the U.S. one.[394] Therefore, although U.S. case law is nonbinding for the EPO, it raised that it may provide a persuasive source of authority.[395]

A different topic, which also must be touched upon is the research exemption issue. It has been criticized that in the context of U.S. intellectual property that a lot of fair-use protections have recently been eliminated, an example being the Digital Millennium Copyright Act.[396] The Act through its definition of the term "circumvent a technological measure"[397], disallows any bypass of a copy-protection scheme, even for legal purposes, thus preventing the public from fair use of such information.[398] Because of this, some have even reached the conclusion that these new provisions may lead to the creation of "cyber-vassals and cyber-lords."[399] In the case of patent law, the *Life*

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390 EPC, *supra* note 319, art. 57.
391 Biotech Directive, *supra* note 321, art. 5(3).
392 *Id.*, Recital 24.
393 DU VALL, *supra* note 310, at 377.
394 *Id.*
395 *Id.*
396 Dibadj, *supra* note 14, at 1057; To amend title 17, United States Code, to implement the World Intellectual Property Organization Copyright Treaty and Performances and Phonograms Treaty, and for other purposes (Digital Millennium Copyright Act) (codified as amended in scattered sections of 17 U.S.C.) [hereinafter DMCA].
397 *Id.* §1201 Circumvention of copyright protection systems
(a) Violations Regarding Circumvention of Technological Measures.—(1)(A) No person shall circumvent a technological measure that effectively controls access to a work protected under this title. The prohibition contained in the preceding sentence shall take effect at the end of the 2-year period beginning on the date of the enactment of this chapter.
(3) As used in this subsection—
(A) to "circumvent a technological measure" means to descramble a scrambled work, to decrypt an encrypted work, or otherwise to avoid, by-pass, remove, deactivate, or impair a technological measure, without the authority of the copyright owner; and
(B) a technological measure "effectively controls access to a work" if the measure, in the ordinary course of its operation, requires the application of information, or a process or a treatment, with the authority of the copy-right owner, to gain access to the work.
398 Dibadj, *supra* note 14, at 1057 ("[T]he Digital Millennium Copyright Act (DMCA), essentially eliminates fair use of information delivered by digital means. It does this by not allowing the bypass of any copy-protection scheme, even if it is to make a legal copy-for instance, for personal use. To the extent that intellectual property will be increasingly delivered by digital means, this prevents the public from taking advantage of new information delivery mechanisms.").
399 *Id.* at 1057-1058.

Sciences v. Merck KgaA[400] decision failed to clarify the issue of the research exemption. The topic of the U.S. research exemption and tweaks to U.S. patent law in this regard will be discussed in more detail later in the chapter devoted to legislative solutions.

The U.S. is an example of a very narrow treatment of the research exemption.[401] The E.U. approach, although considered to apply the exemption in a broader fashion,[402] is on the other hand is a lot more divisive, as Europe is yet to implement a regulation dealing with the issue of a research exemption.[403] Therefore, at the present moment the breadth of the said exemption in the E.U. is the domain of individual member state courts.[404]

3. PATENTING LIVING ORGANISMS AND THE HUMAN GENOME

Gene technology is at the heart of modern medical research.[405] As mentioned before, the 1980s were a time of great medical advancement, which was due to the fact that companies like Biogen, Amgen, and Chiron used the aforementioned technology to create the first generation biopharmaceuticals.[406] Examples of these advancements were the first recombinant protein (human insulin), recombinant vaccine (for hepatitis B), monoclonal antibody (against the rejection of transplant kidneys), oligonucleotide (against cytomegaloviruse retinitis in AIDS patients), the human growth hormone, erythropointin, alphainterferon, or interleukins.[407] The importance of human gene technology is summed up in the following paragraph:

> Scientists estimate that over 4,000 diseases stem from mutated genes. Approximately 1,800 individual genes have been linked to a specific disease as of April 2000. Genes hold the necessary information for the development of therapies, drugs, and diagnostic tests that can provide life-saving information and innovation. Human gene patent innovation can be a matter of life or death or, at a minimum about improving the quality of life for individuals with genetic diseases.[408]

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400 *Merck KGaA, Petitioner v. Integra Lifesciences I, Ltd., et al, 545 U.S. 193 (2005)*.
401 DU VALL, *supra* note 310, at 261.
402 *See id.* at 261-262.
403 See *Italy, Spain take patent fight to court*, EURACTIV, May 31, 2011, *available at* http://www.euractiv.com/en/innovation-enterprise/italy-spain-take-patent-fight-court-news-505264.
404 DU VALL, *supra* note 310, at 261, 263.
405 Li, *supra* note 48, at 349
406 *Id.* at 350.
407 *Id.*
408 *Id.* 365 (*quoting* Biotechnology Indus. Or., Primer: Genome and Genetic Research, Patent Protection and 21st Century Medicine 16 (2000), *available at* http://www.bio.org/ip/primer/.)

But despite its life-saving importance, the issue of using human genes has sparked ethical debates. Among these debates lies the tragedy of the anticomons. To therefore see the entirety of the tragedy, it is also important to understand the gene debate.

Quite often, as a political example, the joint statement of March 14, 2000 of Mr Bill Clinton and Tony Blair, is brought up, which underlined that "raw fundamental data on the human genome, including the human DNA sequence and its variations, should be made freely available to scientists everywhere."[409] But this statement should also be raised to underline the importance of terminology, namely the difference between the term *gene* and *genome*. The latter refers to the totality of an organism's complement of DNA present in each cell, which is unpatentable subject matter.[410] The former, on the other hand, are particular sections of DNA and are patentable.[411]

Leaving the joint statement and terminology aside however, and coming back to the issue of the importance of these gene-based inventions, it seems once again prudent to underline that this is not only a life-saving industry, but also a moneymaking one.[412] Thus, it seems hardly surprising that the gene patenting is an investment magnet.[413] With investment comes regulation, and with that comes disclosure. Bringing DNA within the ambit of patent laws enables one to publish one's findings. This is another argument in favor of gene patents.

> Such publication often occurs ahead of any publication in the scientific literature and can therefore be a primary source of information about the invention. Others benefit from such early publication because they can undertake experimental research without delay and with less risk of inefficiently duplicating the work, which facilitates scientific and medical progress.[414]

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[409] *Id.* at 347 (*quoting* Charles Arthur, *Celera Leads Way in High Stakes Chase to Patent Our Genes*, Indep. (London), Mar. 16, 2000, at 21); *see also* DU VALL, *supra* note 310, at 371; Gitter, supra note 372, at 1629.
[410] Gitter, *supra* note 372, at 1628-1629.
[411] *Id.* at 1629.
[412] Li, *supra* note 48, at 350.
[413] *Id* at 362.
[414] *Id.* (*quoting* Mike Scott & Jill Valentine, *Gene Patenting and Medical Research: A View from a Pharmaceutical Company*, 3 Nat. Rev. Drug Discovery 364, 365 (2004)).

And indeed the core argument of the proponents of gene patenting is that drug discovery has not been impeded in the U.S.[415] All of the mentioned arguments in favor of DNA patents have nevertheless been fervently attacked.

As mentioned before, Article 27 of TRIPS does not define the term invention.[416] *A fortiori*, it does not define whether human genes are inventions, or patentable subject matter.[417] And this is more than just a question concerning mere definitions, as the debate rages whether human genes should actually be considered as inventions.[418] There are voices raising that "genes are naturally occurring entities existing in living organisms and are not invented but discovered."[419] One of such voices was Mike Stratton who is the head of the Institute of Cancer Research in London.[420] In his opinion patenting DNA "is a form of colonization."[421] These and more arguments will be touched upon later, as one must first see what the law is before one can start criticizing it. For now, the patenting of genes seems to be a fact of law.

As mentioned earlier, there exists a common theme prevailing throughout different laws concerning the patenting of genes, and it is isolation or purification. It would be most prudent to concentrate on these requirements, because with isolation and purification comes the question: what is isolation and purification? From a scientific standpoint, every gene needs to be isolated via technical means, in order to be discovered.[422] To achieve this scientists separate the genes, replicate, and isolate them.[423] This process should be explained in more detail.

"Doexyribunucleic acid (DNA) is the primary carrier of hereditary information for life on Earth."[424] It is composed of four standard nucleotides: adenine, thymine, cytosine, and guanine, all of which are linked to their complimentary base pair.[425] Due to

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[415] *Id.* 364 (*referring to* John P. Walsh et al., *Working Through the Patent Problem*, 299 Sci. 1021 (2003); John P. Walsh, *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., 2003)..
[416] *Id.* at 350; TRIPS, *supra* note 320, art. 27.
[417] Li, *supra* note 48, at 350.
[418] *Id.* at 347.
[419] *Id.* at 350.
[420] *Id.* at 351.
[421] *Id.* (*quoting* Gitter, *supra* note 372, at 1631).
[422] *Id.* (*quoting* Dennis Schertenleib, *The Patentability and Protection of DNA Based Inventions in the EPO and the European* Union, 25 Eur. Intell. Prop. Rev. 125, 127 (2003)).
[423] *Id.*
[424] Chester J. Shiu, *Of Mice and Men: Why an Anticommons Has not Emerged in the Biotechnology* Realm, 17 Tex. Intell. Prop. L.J. 413, 417 (2009).
[425] *Accord Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 193-200 (S.D.N.Y. 2010), as amended (Apr. 5, 2010), aff'd in part, rev'd in part sub nom. *The Ass'n For*

this property, called base pairing, DNA ordinarily exists as a double helix, consisting of two intertwined strings of chemically bound DNA.[426] Within that structure exist genes, the basic units of heredity, which are typically thousands of nucleotides long and usually encode proteins.[427] Thus "[t]he genetic code is the link between DNA and protein."[428] Genes are responsible for defining physical traits, like eye color, sex, skin tone, but also the susceptibility for certain conditions, such as obesity.[429] Proteins are encoded through building blocks – amino acids - via three nucleotide combinations, referred to as codons, which correspond to one of twenty amino acids.[430] Without delving into the details, it is sufficient to state that the entire process of protein encoding is conducted via a relay of individual molecules, like messenger ribonucleic acid (mRNA) and transfer ribonucleic acid (tRNA). Only some segments of the DNA however code proteins, they are called *exons*.[431] Non-coding segments are referred to as *introns*.[432]

The importance of the above knowledge is obvious for science, due to the universal nature of DNA.[433] Since every person's DNA is practically identical, it does not matter whose DNA is selected.[434] Scientists have a plethora of tools and methods as far as genetic engineering is concerned, e.g. they may extract, purify, or synthesize DNA.[435] The definitions developed by Judge Sweet will be sufficient for the development of this thesis' topic:

> [T]he term "extracted DNA" will be used to refer to DNA that has been removed from the cell and separated from other non-DNA materials in the cell (e.g., proteins); "purified DNA" will be used to refer to extracted DNA which has been further processed to separate the particular segment of DNA of interest from the other DNA in the genome; and "synthesized DNA" will be used to refer to DNA which has been synthesized in the laboratory.[436]

Molecular Pathology v. U.S. Patent & Trademark Office, 2010-1406, 2011 WL 3211513 (Fed. Cir. July 29, 2011)

[426] *Id.*

[427] *Id.*; Eileem M. Kane, *Splitting the Gene: DNA Patents and the Genetic Code*, 71 Tenn. L. Rev. 707, 708-709 (2004).

[428] Kane, supra note 427, at 709.

[429] *Accord Ass'n for Molecular Pathology* 702 F. Supp. 2d at 194.

[430] *Id.*

[431] *Id.*

[432] *Id.*

[433] *See* Lopez-Beverage, *supra* note 310, at 49.

[434] *Id.*

[435] *Ass'n for Molecular Pathology* 702 F. Supp. 2d at 196.

[436] *Id.*

The Last of these terms refers to complementary DNA (cDNA), which is a man-made particle.[437] It derives its name from the fact that it is a complementary particle to mRNA, a particle created from DNA, which contains only exons.[438] During the process of reverse transcription cDNA is generated from mRNA.[439] This is in other words a cloning process.[440]

From a market-based standpoint this is sufficient to claim that the cDNA is an entirely human-created invention, due to the fact that it has been purified, and left the world of nature.[441] Thus, some say that "[t]he DNA we use is created and not discovered."[442] This is a time-consuming and costly process, which in the opinion of the supporters of gene patenting, adds credibility to the notion that such work should be rewarded with a patent right.[443] Furthermore, the nucleotide sequence is not obvious per se.[444] On the other hand it has been argued that gene sequences have controversially received patent protection although "any monkey can generate numerous unidentified gene sequences."[445] This is due to the fact that the extraction and determination of the nucleotide sequence is obvious.[446]

Nevertheless, the aforementioned brings back the arguments against gene patenting. The procedure, which was described has been presented in a very comical manner in the following paragraph:

> Entities that claim patents on a gene with a particular utility is akin to a company that tries to patent the word "the." The company claims to have isolated the word by taking it out of the sentence that usually surrounds it. The company has discovered that it can give a description of the word "the" – it has three letters in a specific order, etc. In this way, the company has also proven it is a new and novel invention because "the" does not occur naturally in language without at least a noun. The company says its researchers have isolated and copied the word. As well, with its computers, the company claims to have discovered that the word "the" occurs in, say, 5% of sentences that are "soothing." The company says it has found

[437] *Id.* at 198-199.
[438] HELENA ŻAKOWSKA-HENZLER, WYNALAZEK BIOTECHNOLOGICZNY PRZEDMIOT PATENTU 40 (Anna Raciborska & Anna Kaniewska eds. Wydawnictwo Naukowe SCHOLAR 2006).
[439] Lopez-Beverage, supra note 310, at 50.
[440] *Id.*
[441] Li, *supra* note 48, at 347.
[442] *Id.* 352.
[443] *Id.* at 349.
[444] *Id.* at 355 (*referring to* Kate H. Murashige, *Genome Research and Traditional Intellectual Propery Protection – A Bad Fit?*, 7 RISK: Health, Safety & Environment 231 (1996), *available at* http://www,piercelaw.edu/risk/vol7/summer/murashig.htm).
[445] *Id.*
[446] *Id.* (*referring to* Kate H. Murashige, supra note 442, at 231).

> a correlation between "the" and soothing sentences. In its patent application, therefore, the company claims that the "utility" of the word "the" is that it has a correlation to soothing sentences. This company hopes to produce products from the word "the," perhaps a whole series of sentences that are soothing.[447]

Such a humorous comparison can be attributed the fact that gene patent protection is analogous to the protection afforded to chemical compounds.[448]

Gene patenting has been criticized also on the basis of the law of nature doctrine.[449] Today's gene patenting has been compared to the issue touched upon by the U.S. Supreme Court in the *O'Reilly v. Morse*[450] case.[451] The widely-known Samuel Morse received a patent for an apparatus capable of transmitting signal at a distance, i.e. an electromagnetic telegraph.[452] The most relevant of his patent claims included the eighth claim:

> 'Eighth. I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances, being a new application of that power, of which I claim to be the first inventor or discovered.'[453]

In essence, Morse claimed the principle of electromagnetism.[454] The majority thus invalidated the patent on the basis of its breadth, as the inventor "claims the exclusive right to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance."[455]

A similarity may be drawn to the aforementioned case and DNA patenting. Drawing from the definition of a law of nature, which is "an invariant relationship that governs the interaction of two or more physical entities,"[456] one may point that "[t]he genetic code describes a discrete set of fixed relationships between DNA and protein,

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447 Lopez-Beverage, *supra* note 310, at 37-38.
448 *See* DU VALL, supra note 310, at 364.
449 Kane, *supra* note 427, at 747-749.
450 *O'Reilly v. Morse*, 56 U.S. 62 (1853).
451 *See* Kane, supra note 427.
452 *O'Reilly v. Morse*, 56 U.S. 62, 63 (1853).
453 *Id.*, at 86.
454 Kane, *supra* note 427, at 748.
455 *O'Reilly v. Morse*, 56 U.S. 62, 112 (1853).
456 Kane, *supra* note 427, at 751.

mediated through RNA intermediaries.''[457] From this perspective, DNA embodies a law of nature due to the mentioned fixed relationship and expression.[458] The enablement of granting private rights on a finite number of expressions is in essence an enablement of patenting a law of nature.[459]

Moreover, there seems to be a degree of agreement among European scholars that the European Biotechnology Directive draws a blurry line when it comes to biotechnological inventions and mere discoveries.[460] The crux of the argument holds that since mere isolation is enough to constitute a biotechnological invention, then the entire essence of such an invention is only in its definition.[461] Thus, the line between an invention and a discovery is not only a blurry one but also an arbitrary one.[462] Interestingly enough, similar criticism in the U.S. has not discouraged the USPTO from arguing in favor of gene patents.[463] As the *Final Guidelines For Determining Utility Of Gene-Related Inventions* state:

> An inventor can patent a discovery when the patent application satisfies the statutory requirements. The U.S. Constitution uses the word ''discoveries'' where it authorizes Congress to promote progress made by inventors ….
> Thus, an inventor's discovery of a gene can be the basis for a patent on the genetic composition isolated from its natural state and processed through purifying steps that separate the gene from other molecules naturally associated with it.[464]

The legal dispute on whether genes are patentable subject matter has been the subject of the U.S. Court of Appeals for the Federal Circuit's decision in the case of *The Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*.[465] The case concerned the controversial topic of Myriad Genetics' patents on two human genes – BRCA1 and BRCA2 – and their mutations associated with a predisposition to breast and ovarian cancers.[466] Some of Myriad's patents encompassed strands of DNA, which

[457] *Id.* at 752.
[458] *Id.* at 753.
[459] *Id.* at 754.
[460] *See* DU VALL, *supra* note 310, at 370; ŻAKOWSKA-HENZLER, *supra* note 438, at 118.
[461] ŻAKOWSKA-HENZLER, *supra* note 438, at 118.
[462] DU VALL, *supra* note 310, at 37o.
[463] *Id.* at 370-371.
[464] USPTO Guidelines, *supra* note 384, at 1093.
[465] *The Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 2010-1406, WL 3211513 (Fed. Cir. July 29, 2011).
[466] *Id.* at 1.

did not differ in its nucleotide sequence from that, which can be found in nature.[467] To understand the above case, it is imperative to briefly describe the lower court's decision rendered by Judge Maxwell Sweet.[468] In his opinion Judge Sweet described the implications of gene patents on research and development, clearly mentioning the tragedy of the anticommons.[469] The judge further mentioned the chilling effects of DNA patents, especially those on BRCA 1 and 2:

> A survey of laboratory directors … found that 53% decided not to develop a new clinical test because of a gene patent or license, and 67% believed that gene patents decreased their ability to conduct research …. In addition to labs that have ceased performing BRCA1/2 genetic testing, labs have avoided or refrained from developing tests for BRCA1 and BRCA2 as a result of the patents held by Myriad.[470]

The essence of the dispute however concerned the BRCA1 and 2 genes. The dispute between the plaintiffs and Myriad was in essence the interpretation of the term *DNA patent*.[471] Myriad's interpretation favored a chemical compound approach, whilst the plaintiff's interpretation concentrated on the nucleotide sequence.[472] For the court, the issue revolved around whether Myriad's claims fulfilled the *markedly different standard*, established in the case of *Diamond v. Chakrabarty*.[473] This standard led the court to the conclusion that Myriad's focus on the chemical compound side of DNA was erroneous, as it "fails to acknowledge the unique characteristics of DNA that differentiate it from other chemical compounds."[474] This uniqueness of genes is the fact that they are carriers of information.[475] Thus, the Myriad patents on isolated BRCA1/2, in the court's judgment, did not hold water.[476]

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[467] *Id.* at 15.
[468] *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181 (S.D.N.Y. 2010), as amended (Apr. 5, 2010), aff'd in part, rev'd in part sub nom. *The Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 2010-1406, 2011 WL 3211513 (Fed. Cir. July 29, 2011)
[469] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 208.
[470] *Id.* at 208-209.
[471] *Id.* 702 F. Supp. 2d at 216-217.
[472] *Id.*
[473] *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (establishing that a bacterium needs to possess markedly different characteristics from any [bacterium] found in nature).
[474] *Ass'n for Molecular Pathology*, 702 F. Supp. 2d at 228.
[475] *Id.* at 228 ("This informational quality is unique among the chemical compounds found in our bodies, and it would be erroneous to view DNA as 'no different[ ]' than other chemicals previously the subject of patents.")
[476] *Id.* at 229.

The court also dealt with the issue BRCA1/2 cDNA molecule patents.[477] To the court, the fact that these patents covered only protein coding exons did not mean that they were markedly different.[478] The court argued that the mentioned coding sequences were identical to those found in nature, which are the result of the splicing of pre-mRNA into mRNA.[479] Furthermore, they are in actuality already found in the human organism in the form of pseudogenes.[480] Thus, what the court did was to establish that both an isolated form of DNA and cDNA are in this case unpatentable subject matter.

On appeal Myriad argued that its isolated BRCA1/2 molecules were "patent eligible because it is … 'a nonnaturally occurring composition of matter' with 'a distinctive name, character, and use'."[481] The crux of the case therefore concerned the issue whether isolated DNA was patentable subject matter.[482] The court tackled the issue through the scope of, once again, the markedly different standard.[483] From this standpoint, the court argued that the distinction between a product of nature and a human-made invention depends on the change in the claimed composition's identity when comparing it with what exists in nature.[484] And from this standpoint the conclusion was that there indeed was a difference from a naturally occurring particle, as "isolated DNA must be removed from its native cellular and chromosomal environment, it has also been manipulated chemically so as to produce a molecule that is markedly different from that which exists in the body."[485] Thus what makes isolated DNA eligible for patent protection is the sheer fact of its isolation.[486] Namely, the fact of isolation produces a distinct molecule, one which is not covalently bonded to other genetic materials.[487] The approach towards DNA molecules adopted by the majority therefore, was from a purely chemical standpoint.

The dissent criticized the opinion on the basis that the court treated isolated DNA molecules as purely a chemical substance, and did not approach the issue from a

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[477] *Id.* at 230-232.
[478] *Id.* at 230.
[479] *Id.*
[480] *Id.*
[481] *The Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 2010-1406, WL 3211513 (Fed. Cir. July 29, 2011), at 15.
[482] *Id.* at 15-20
[483] *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).
[484] *The Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 2010-1406, WL 3211513 (Fed. Cir. July 29, 2011), at 17.
[485] *Id.*
[486] *Id.* at 18.
[487] *Id.* at 17.

geneticist's viewpoint.[488] This is due to the fact that even Myriad's patent claims are defined by an amino acid sequence,[489] and further because DNA is a different type of chemical substance.[490] Moreover, Judge Bryson added, that the argument that chemical bonding makes the world of a difference is erroneous, because "there is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken."[491]

As far as cDNA patents are concerned, the court accepted their patentability, due to the fact that it is man-made.[492] What is worth mentioning however is Judge Bryson's underlining of the negative implications of the broadness of Myriad's patents.[493] At this juncture, the dissent touches upon the issue of the tragedy of the anticommons:

> Broad claims to genetic material present a significant obstacle to the next generation of innovation in genetic medicine …. New technologies are being develop to sequence many genes or even an entire genome rapidly, but firms developing those technologies are encountering a thicket of patents…. In order to sequence an entire genome, a firm would have to license thousands of patents from many different licensors. Even if many of those patents include claims that are invalid for anticipation or obviousness, the costs involved in determining the scope of all of those patents could be prohibitive.[494]

Another hot topic is the already mentioned issue of Expressed Sequence Tags (ESTs). Their importance, as mentioned earlier, reveals itself when one endeavors to identify the position of a gene within the genome.[495] To briefly recap, ESTs are partial sequences of cDNA clones, which correspond to mRNA.[496] These small copies are used as research tools.[497] Research tools are referred to as *upstream* products, as they are used in the creation of end-products, i.e. *downstream* inventions.[498] The NIH application for an EST patent opened the door for a plethora of other gene patents for anonymous

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488 *Id.* at 40 (Bryson J. dissenting).
489 *Id.*
490 *See* DU VALL, *supra* note 310, at 364.
491 *The Ass'n For Molecular Pathology v. U.S. Patent & Trademark Office*, 2010-1406, WL 3211513 (Fed. Cir. July 29, 2011), at 39 (Bryson J. dissenting).
492 *Id.* at 43.
493 *Id.* at 42-45.
494 *Id.* at 44.
495 *See* DU VALL, *supra* note 310, at 365.
496 Lopez-Beverage, *supra* note 310, at 47.
497 *Id.* at 47-48.
498 Ramirez, *supra* note 203, at 360.

gene fragments.[499] This in turn led various companies to sue other companies in other countries and even the countries themselves, including but not limited to suits over research tools.[500] An example of a research tool is polymerase chain reaction (PCR) technology: "a process that 'selectively and exponentially amplifies (or multiplies) a specific region of DNA, producing quantities of DNA sufficient for experimentation and analysis.'"[501] It is nowadays a standard and widely-used research technique.[502] However, the wide granting of patents for research tools may be counterproductive for downstream innovation, because if patents for upstream discoveries are sufficiently broad, it may block access to basic tools.[503] On the other hand, it may be raised that a research tool, when used as such, falls under a research exemption.[504] Indeed its very name suggests that the ordinary purpose of a research tool is research. Thus, what more clear application of a research exemption could there be?

Criticism of gene patenting has also reached the core of patent law, namely the notion that patents create incentives and reward research.[505] Namely, many of the currently patented genes are the result of governmental funding donated to the Human Genome Project.[506] The gist of the criticism is that "[t]he public, therefore, pays twice, first by funding the research and then by having to pay for the end-products because of the monopoly held by the gene patentee."[507]

The abovementioned is connected with the economic doubts whether indeed gene patents bring more societal benefits. Namely, what is being raised is that gene patents impose high royalty fees on healthcare providers who test patients for genetic predisposition to diseases.[508] The mentioned BRCA1/2 example illustrates how human

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499 HELLER, *supra* note 120, at 61; Heller & Eisenberg, *supra* note 65, at 699 ("[I]n 1991, NIH pointed the war toward patenting anonymous gene fragments with its notorious patent applications on expressed sequence tags ....").
500 *See* Lopez-Beverage, *supra* note 310, at 49.
501 Ramirez, *supra* note 203, at 361 (*quoting* Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 Wash. L. Rev. 1, 13 (2001)).
502 *Id.*
503 Lopez-Beverage, *supra* note 310, at 79; *see also* Li, *supra* note 48, at 363 (*referring to* Long, *supra* note 45, at 824).
504 *See* DU VALL, *supra* note 310, at 261.
505 Li, *supra* note 48, at 364 (*referring to* Andrew Pollack, *U.S. Hopes to Stem Rush Toward Patenting Genes*, Patriot Ledger, June 28, 2002, at 18.).
506 *Id.*
507 *Id.*
508 *Id.* at 363.

gene patents inflate the costs of healthcare.[509] The egregiousness of the BRCA1/2 patents is even stronger when looking at Europe where an opposition procedure initiated by the Institute Curie, and targeted at Myriad's patents led to the seemingly strange narrowing of said patents.[510] An article in *Science* expresses the moral outrage towards the treatment of the Ashkhenazi Jewish women whom these patents hurt the most:

> In Europe, a collation of research institutes challenged Myriad's patents, invalidating some and limiting others. Because of the paring back of Myriad's rights, the tests are now free for everyone except Ashkenazi Jewish women, who must pay Myriad's licensing fees. The mutations that are still covered by Myriad's remaining patents are most commonly found in Ashkenazi women. By law, a doctor must ask a woman if she is an Ashkenazi Jew, which has provoked howls from geneticists.[511]

In a 2008 decision by the Technical Board of Appeal of the EPO, the Myriad patents were upheld but narrowed to "detection of frameshift mutations - mutations which downstream from the mutation site result in incorrect coding and premature termination of translation."[512] This included Myriad's claims to "determining whether there is germline alteration 185delAG–>ter39 in the BRCA1 gene in a tissue sample of said subject said alteration indicating a predisposition to said cancer."[513] The mentioned claimed mutation is most common among Hispanic and Ashkenazim Jewish populations.[514] The situation in Europe is thus uncertain, as Myriad has indeed stronger patent rights but on the other hand, it must "contend with diagnostic use exemptions and compulsory licensing provisions in several national jurisdictions."[515] There are more examples showing how enforcement of a patent caused prices to skyrocket. One such example is the Canavan disease, for which free tests stopped being offered due to patents right of a company,[516] or the screening for the Downs Syndrome.[517] This also affects the

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509 *Id.* (*quoting* Melissa E. Horn, *DNA Patenting and Access to Healthcare: Achieving the Balance Among Competing Interests*, 50 Clev. St. L. Rev. 253, 270 (2002-2003).
510 *Accord* Cook-Deegan et al., *Impact of gene patents and licensing practices on access to genetic testing for inherited susceptibility to cancer: Comparing breast and ovarian cancers with colon cancers*, 12 Genetics in Medicine S15, *available at* http://journals.lww.com/geneticsinmedicine/Fulltext/2010/04001/Impact_of_gene_patents_and_licensing_practices_on.4.aspx.
511 Stix, supra note 332, at 83.
512 *EPO Appeal Board upholds controversial patents for breast and ovarian cancer genetic testing*, Marks&Clerk Solicitors, 9 December 2008, *available at* http://www.marks-clerk.com/uk/solicitors/news/newsitem.aspx?item=229.
513 T 0666/05 [2008] E.P.O.R. 3 (Technical Bd. App. 2005)
514 Cook-Deegan et al., *supra* note 502.
515 *Id.*
516 Li, *supra* note 48, at 365.

production of drugs, as 12-14 percent of their cost is because of the royalties paid to patent holders.[518]

Moreover, the ineffectiveness of gene patents may sometimes be due to their broadness, as "a gene patent can be broad enough to cover any commercial use of the gene and the gene product."[519] This may in turn lead to underuse.[520] First, because many diseases are polygenic, which means that multiple genes are involved in their manifestation.[521] And second, because licensing fees may be too high, thus limiting further research.[522] The probability of the latter occurring is strengthened by the fact that all genes are of a unique nature and thus have no substitutes, which prevents designing around them.[523]

Finally, gene patenting, especially human DNA, raises moral objections. As mentioned earlier, a major difference between U.S. and E.U. patent law is their approach to morality.[524] However, as far as the patenting of human genes is concerned, it is acceptable in both legal regimes.[525] The Howard Florey/Relaxin case concerned a patent entitled "Molexular cloning and characterization of a further gene sequence coding for human relaxin"; the Opposition Division of the EPO stated in its decision that "the allegations that human life is being patented were unfounded, because DNA did not constitute life, and a human being could not be reconstructed from the total of human genes …" and that "the claims were directed towards the cDNA, because the amino acid sequences set out in the claims did not include the amino acids related to the intron found in the genomic DNA encoding the H2 relaxin." [526] The decision was subsequently appealed and decided by the Technical Board of Appeal on 23 October

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[517] *Id.* at 364 (*referring to* Andrew Pollack, *U.S. Hopes to Stem Rush Toward Patenting Genes*, Patriot Ledger, June 28, 2002, at 18.).
[518] *Id.*
[519] *Id.* at 363 (*referring to* John J. Doll, *Biotechnology: The Patenting of DNA*, 280 Sci. 690 (1998)).
[520] *See id.* (*referring to* Long, *supra* note 45, at 827).
[521] *Id.*
[522] *Id.*
[523] *Id.* (*referring to* Heller & Eisenberg, supra note 65, at 700 ("[A]ll genes are unique and have no substitution and, therefore, cannot be 'designed around.' If researchers want to work on a cure for a genetically-based disease, they must use the gene that causes the disease.").
[524] *Id.* at 353.
[525] *See* Gitter, supra note 372, at 1624-1625.
[526] Li, *supra* note 48, at 353, 354.

2002.[527] The Board found that within the meaning of the EPC, human DNA is patentable subject matter.[528] The appeal was thus dismissed.[529]

Patents on DNA may raise objections, but it seems that they are here to stay, regardless of whether such patents indeed patent a law of nature. The question remains whether the continuing patents on genes will lead to a gridlock. There indeed is evidence suggesting that in the context of the pharmaceutical industry.

4. THE PROBLEM OF PHARMACEUTICALS

The problems facing today's pharmaceutical industry can be considered an excellent summary for this chapter. This summary shows the ramifications of all the issues mentioned in the preceding chapters on a larger scale.

The great biotechnological boom of the 1980s enabled the pharmaceutical companies in the U.S. to create their own research facilities or acquire firms, which would conduct this research for them.[530] Said research was often conducted by university spin-offs.[531] Such a turn of events is not surprising when taking into consideration the money at stake. As already mentioned, gene technology is at the heart of medical research.[532] As an example, the sale of erythropoietin and similar products enabled Amgen to make $3 billion annually.[533] However, due to the high stakes involved, and the multiplicity of patents, the battles between pharmaceutical companies become so fervent that a lot of them waste their efforts and resources on litigation.[534] This is considered to be a ramification of defensive patenting, a phenomenon contributed to the tragedy of the anticommons.[535] The battle, due to so many patents, raises the argument that "[t]he proliferation of weak patents can be a strong drag on innovation."[536]

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[527] Florey/Relaxin, *supra* note 370.
[528] *Id.* at 10-11 ("It follows from the text itself that the matter mentioned above is not to be considered as an exception to patentability .... [The patent claims], thus, answer the definition of patentable elements of the human body....").
[529] *Id.* at 13.
[530] *See* Li, *supra* note 48, at 349 ("By the 1980s, big pharmaceutical companies in the United States started to realize the power of biotechnology and began to establish their own research and development laboratories or acquire these firms.").
[531] *Id.*
[532] *Id.*
[533] *Id.* at 350.
[534] HELLER, *supra* note 120, at 51.
[535] *Cf. id.* at 59.
[536] *Id.* at 53.

A notable example of the danger of an anticommons in the pharmaceutical industry are patents on receptors.[537] Receptors are important for the industry, because they enable to assessment of the therapeutic and side effects of a potential product at the preclinical stage.[538]

Furthermore, the stakes concerning pharmaceutical products are not related to a national forum but should be viewed from an international standpoint. It is indeed hard to imagine a similarly international issue, as health. The words of Merck's vice president, Bennett Shapiro express the danger of the tragedy of the anticommons in the following words:

> [C]ompounds for schizophrenia often develop other disorders some of which resemble Parkinson's disease, another disease involving the dopamine system. A rational approach to discovery of improved schizophrenia drugs would be to target specific dopamine receptors. But if different companies hold patents on different receptors, the first step on the path to an important and much needed therapeutic advance can be blocked.[539]

And this is indeed a plausible scenario, as defensive patenting is also a means of gaining leverage in license negotiations.[540] The plausibility is strengthened by the fact the NIH's Working Groups on Research Tools has already reported that difficulties with negotiating license agreements sometimes interfered with the widespread dissemination of research tools, especially when taking into consideration the emergence of the previously mentioned patent trolls.[541] Moreover, a study conducted by the sociologist John Walsh indicated that scientists are conducting their research outside the law.[542] The report stated that "[u]niversity researchers have a reputation for routinely ignoring IP rights in the course of their research."[543] And indeed the costs associated with the investigation of patents does not make following the law an easy task.[544] Moreover, a similar study showed that everyone involved in biomedical research considers the patent land-

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537 *See* Heller & Eisenberg, *supra* note 65, at 699.
538 *Id.*
539 HELLER, *supra* note 120, at 53.
540 *Id.* at 58.
541 *Id.*; Ramirez, *supra* note 203. at 361.
542 HELLER, *supra* note 120, at 66 (*noting* John P. Walsh et al., *Effects of Research Tool Patents and Licensing on Biomedical Innovation*, *in* PATENTS IN THE KNOWLEDGE-BASED ECONOMY 285 (Wesley M. Cohen & Stephen A. Merrill eds., National Academies Press 2003, *available at* www.nap.edu/catalog.php?record_id=10770)).
543 *Id.* (*quoting* John P. Walsh et al., *supra* note 542, at 324).
544 *Id.* ("[T]o investigate ownership of the intellectual property used in a single campus lab, the University of Iowa had to contact seventy-one different entities and spend tens of thousands of dollars in background checks.").

scape as being more complicated.[545] On the other hand, nobody reported that worthwhile projects were halted due to lack of access to research tools.[546] The reason for this is that the biotech industry developed its own solutions for the problem of the tragedy of the anticommons.[547] This will be explored later.

All of the abovementioned developments are associated with the passing of the Bayh-Dole Act - the Pandora's box, as some would call it – which allegedly started the development of the tragedy of the anticommons.[548]

To sum up, the tragedy of the anticommons may not necessarily be visible. Its ramification may however be that "[s]cientists simply gravitate away from congested fields," especially due to the withholding of diagnostic tests.[549] Thus, the biomedical industry is shrinking as is the drug approval rating, while the research and development spending is rising.[550] This would surely be an explanation why companies quietly abandon research and development.[551] If so, then addressing the anticommons issue becomes a necessity, if progress is to continue. This is not however a definite explanation, and thus the anticommons theory has taken heavy criticism. In the final chapter this criticism will be explored.

[545] Walsh et al., *Working …*, *supra* note 415, at 1021.
[546] *Id.*
[547] *Id.*
[548] *Cf.* HELLER, *supra* note 120, at 58.
[549] *Id.* at 67.
[550] *Id.* at 59.
[551] *Id.* at 68-69.

V. THE DILEMMA: CRITICIZE OR FEND THE TRAGEDY OFF?

The anticommons problem is not just limited to intellectual property. It is a collective choice concept, which encompasses constitutional and administrative law. For some, a way to solve the problem may even be to reshape democracy.[552] This may be done through the abolishing of the public-private distinction.[553] To support such a notion its proponents quote Justice Holmes' dissent in *Lochner v. New York* who warned that "a constitution is not intended to embody a particular economic theory, whether of paternalism and the organic relation of the citizen to the State or of laissez faire."[554] This is however one of the more extreme opinions. The more classical approach is to solve the anticommons problem either through a market approach or a legislative one.[555] Before however tackling the problem, one should analyze whether the problem indeed exists. Therefore, at the very beginning, the criticisms of the anticommons theory will be described.

1. THE PROBLEM OF OCCURRENCE

The tragedy of the anticommons calls for a completely new look at current patent laws. The logical conclusions stemming from this theory often stand in opposition of those who benefit from the proliferation of patents. But not only are the beneficiaries displeased with what the theory propagates. Strong counterarguments have been put forward by notable scholars questioning the validity of this theory.[556] The critics underline the futility of patent reform.[557] What this movement endeavors to establish is that the *status quo* is the best of both worlds. Interestingly, the same arguments, which are used to differentiate intellectual property law from ordinary property law, are used to prove that the tragedy does not exist.[558]

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552 Dibadj, *supra* note 14, at 1119

553 *Id.* ("Rooted in a nineteenth century ideal of separating public and private law, [FN424] it symbolizes the 'inherent conflict between individualism and collective control that informs the liberal perspective…'...") (*quoting* Karl E. Klare, *The Public/Private Distinction in Labor Law*, 130 U. Pa. L. Rev. 1358, 1422 (1982)).

554 *Lochner v. New York*, 198 U.S. 45, 75-76 (1905) (Holmes J. dissenting); Dibadj, *supra* note 14, at 1119.

555 HELLER, *supra* note 120, at 69-78.

556 *E.g.,* Adelman, *supra* note 199.

557 *See id.* at 302 (*noting* Arti K. Rai & Rebecca S. Eisenberg, *Bayh-Dole Reform and the Progress of Biomedicine*, Law & Contemp. Probs., Spring 2003, at 289, 291).

558 *See id.* ("Unlike traditional agricultural commons, patent policy must contend with a much more complex environment.").

At the heart of the criticism lies the argument that thus far no empirical evidence has been presented to clearly indicate the existence of the tragedy of the anticommons.[559] Rather, it is said, the evidence is to the contrary.[560] As mentioned earlier, it is further raised that the biotech industry itself has developed working solutions to tackle the problem of anticommons property.[561] Among these are: "licensing, inventing around patents, going offshore, the development and use of public databases and research tools, court challenges, and simply using the technology without a license (i.e. infringement)."[562] This is due to four reasons. First, infringement of a research tool is hard to detect.[563] Second, the drug development process lasts a long time, while the statute of limitation expires after six years, i.e. before the infringement is discovered.[564] Third, most scientists are under the impression that their actions fall under a research exemption.[565] Fourth, infringement is generally tolerated by intellectual property holders, especially when taking consideration the costs associated with litigation.[566]

Moreover, sheer abstract analysis, which is used to propagate the anticommons theory, is not evidence enough. As empirical evidence that an anticommons has not emerged, a study was conducted by Professor Charles McManis which:

> reviewed and evaluated the empirical evidence to date concerning the impact of upstream university patenting on downstream innovation and found that "little hard empirical evidence has been produced to substantiate ... concerns" that an anticommons exists and that "most - though by no means all - of the most recently unveiled empirical studies suggest that these concerns are exaggerated."[567]

Furthermore, the drastic rise in the number of patents should not provide a reason to worry. After all, "fifty patents distributed over a narrow field of invention may be grounds for concern whereas fifty patents of analogous scope scattered over a broad

559 *Id.* at 303.
560 Mireles, *supra* note 65, at 289
561 Walsh et al., *Working …*, *supra* note 415, at 1021.
562 *Id.*
563 *Id.*
564 *Id.*
565 *Id.*
566 *Id.*
567 Mireles, *supra* note 65, at 289 (*noting* CHARLES R. MCMANIS & SUCHEOL NOH, THE IMPACT OF THE BAYH-DOLE ACT ON GENETIC RESEARCH AND DEVELOPMENT: EVALUATING THE ARGUMENTS AND EMPIRICAL EVIDENCE TO DATE 28 (2006)).

field will not."[568] Moreover, there indeed was a drop in patents, however this was due to the fact that less patents were issued.[569] The number of applicants was still rising.[570] It rose approximately forty percent after 1999.[571] Thus "[i]nnovative output was not in decline."[572]

Since 1994 to 2004 corporate patent ownership gained dominance on the scene, accounting for approximately 80 percent of the patents.[573] And it is from the corporate scene that the criticism towards the anticommons theory was expressed, an example being Craig Venter's, the president of Celera Genomics, whose testimony was heard before a subcommittee of the U.S. House of Representatives:

> A patent was granted on the BRCA1 gene associated with breast cancer in 1993. Since that time, over 721 basic research papers have been published on the BRCA1 gene, and tens of further patent applications on important inventions, including genetic tests related to the BRCA1 gene, have been filed by individuals in universities and companies.[574]

The argument by the big industry can therefore be summed up in that the large number of patents is in actuality socially beneficial. Indeed, many examples substantiating such a claim exist. For example, Roche Molecular Systems stated that "its primary objectives in licensing the technology were to expand and encourage the use of PCR, to receive financial gain from its use, and to preserve the value of the PCR patents."[575]

Moreover, there is no disagreement that since *Diamond v. Chakrabarty*[576] and the enactment of the Bayh-Dole Act, the biotechnology industry has experienced considerable growth since the 1980s.[577] The proponents of these developments quite proudly name the achievements of the industry:

> New biotech drug and vaccine approvals have increased steadily over the past two decades, with a sevenfold increase in the number of biotech

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568 Adelman, *supra* note 199, at 303 (*noting* David E. Adelman, *A Fallacy of the Commons in Biotech Patent Policy*, 20 Berkeley Tech. L.J. 985, 1021-1023 (2005); Carol M. Rose, *Rethinking Environmental Controls: Management Strategies for Common Resources*, 1991 Duke L.J. 1, 5-7).
569 *Id.* at 305 (*noting The Patent System Today and Tomorrow: Hearing Before Subcomm. On Intell. Prop. of the S. Comm on the Judiciary*, 109th Cong. 3 (2005).)..
570 *Id.*
571 *Id.*
572 *Id.*
573 *Id.* at 304.
574 Li, supra note 48, at 364 (*quoting* Ctr. For the Study of Tech. & Soc'y, *Special Focus on Genome Patents*, http://www.tecsoc.org/biotech/focuspatents.htm).
575 Ramirez, *supra* note 203, at 377.
576 *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).
577 Ramirez, *supra* note 203, at 372; Adelman, *supra* note 199, at 302.

> products on the market in the last ten years alone. The amount of capital invested in biotechnology increased from $35 million in 1980 to $14.4 billion in 2002. In fact, by 1990, private industry, not the federal government, represented the single largest source of funding for biotechnology research and development. Revenues in the biotechnology industry increased from $8 billion in 1992 to $28.5 billion in 2001. The first biotech company, Genetech, was founded in 1976, and by 2001 there were 1457 biotech companies in the United States. Almost all research universities now have technology licensing operations, and hundreds of products developed under licenses are currently on the market. These statistics demonstrate that the biotechnology industry has benefited from the increased privatization of upstream research tools, and that strong patent protection for research tools promotes, rather than stifles, downstream innovation.[578]

The beneficiaries also include universities. Indeed there exists a growing trend in university and government patenting for the same period, which is considered evidence of an aggressive pursuit of patents by the former.[579] What is however clearly being raised, is the universities' austerity in letting the dangers of antcimmons property come into existence.[580] Universities have not become subject to pure moneymaking interests and did not enable patents to spread to basic discoveries, and research tools.[581] Examples include MIT, Harvard, and Stanford whose technology transfer policies "favor the patenting of intellectual property that is needed to induce commercial development, but disfavor patenting of research that is far removed from commercial development."[582]

The fact that all entities involved in the patent process recognize the importance of sharing research tools, and are said to have broadened the public domain, is considered to be a positive outcome that prevents anticommons property from developing.[583] As an example of such affirmative steps, the NIH Principles and Guidelines are brought up.[584] Although not binding, they have a persuasive characteristic to them.[585] They are a

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[578] Ramirez, *supra* note 203, at 372-373.
[579] Adelman, *supra* note 199, at 304.
[580] Ramirez, *supra* note 203, at 375.
[581] *Id.* at 380 ("As Professor Arti Rai has observed, 'Even in the face of commercialization pressures, many major research universities have drawn the line at claiming property rights in certain basic scientific discoveries, particularly upstream discoveries that may be useful in a variety of different future research paths or for the development of a variety of commercial products.'").
[582] *Id.* at 380.
[583] *Id.* at 382.
[584] *Cf. id.*
[585] *Cf. id.* at 382-382 ("Although the Principles and Guidelines are only directly applicable to recipients of funding, the NIH urges the entire biotechnology community to adopt similar policies 'so that all biomedical research and develop-ment can be synergistic and accelerated.'").

means of encouraging licensing by acknowledging the usefulness of disseminating research tools.[586]

Finally, any tweaks to the patent system are discouraged, as the system in its current shape is already considered to have struck an appropriate balance.[587] Thus, maintaining the right to exclude on the basis of a patent right should not be touched according to some, undoubtedly American scholars.[588] Further, they argue, changes to the system may discourage disclosure, which would be counterproductive.[589] Moreover, if any problems do exist with the dissemination of research tools, they are due to license agreements, and not due to patent law.[590] Therefore, whether any solutions to the tragedy of the anticommons should be employed is debatable. Neverthelss, there do exist propositions to battle anticommons property, and these solutions will be explored in the final part of this thesis.

2. MARKET-DRIVEN SOLUTIONS

It seems that market-driven to solutions to the tragedy of the anticommons are an expression of utter trust in the classic interpretation of the Coase theorem. What the proponents of these types of solutions state is that because securing a patent is expensive, market actors have too much to waste.[591] Thus, the rational solution to this is to overcome the anticommons problem.[592] In other words: why waste money? What therefore should be done, is to leave the market alone and "trust that sophisticated players can fend for themselves."[593] Some have raised that the simplest solution would be to move research facilities offshore, to international waters.[594] It has been raised also, that the rational pursuit of self-interest leads to the conclusion that simple licensing is the

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586 *Id.* at 382.
587 *Id.* at 385 ("taking away the patent owner's right to exclude would disrupt the patent system's 'carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology . . . in return for the exclusive right to practice the invention for a period of years.'")
588 *Id.* ("The right to exclude is at the heart of the patent monopoly and denying the benefit of the exclusive right would reduce the incentive for disclosing new technologies to the public.").
589 *Id.* at 386 ("If inventors are denied the full benefit of the exclusive rights, they may be less willing to disclose significant discoveries to the public and may alternatively choose to keep their inventions a secret. This result would invariably lead to a decrease in downstream innovation.")
590 *Id.* ("One reason these solutions are inadequate is that problems with the dissemination of research tools stem more from restrictive terms in licensing agreements than from issues of patentability.").
591 HELLER, *supra* note 120, at 69.
592 *Id.*
593 *Id.* at 70.
594 Li, *supra* note 48, at 366 (*referring to* Mike Scott & Jill Valentine, *Gene Patenting and Medical Research: A View from a Pharmaceutical Company*, 3 Nat. Rev. Drug Discovery 364, 366 (2004)).

only way to go.[595] And indeed licensing often works.[596] A study conducted by Jon P. Walsh states that:

> Licensing is routine in the drug industry, and this suggests that the problem of access to patented research tools or upstream discoveries can often be settled contractually.[597]

Others however add to this such endeavors as Wikipedia, as an example of peer production.[598] These however are not the only solutions.

A more competitive market-driven solution are property preventing investments (PPI).[599] They are aimed at preventing competitors from patenting by releasing certain research so that the competitor's accomplishment is no longer novel.[600] In the words of Polonius: "Though this be madness, yet there is method in 't."[601] Namely, by disabling the patenting of less valuable biological materials, it is easier to create a more valuable chemical, which builds on the mentioned materials.[602] There is also a more political explanation to such actions. Pharmaceutical companies also improve their image by enhancing the public domain, the additional benefit of which is "to undermine troublesome patents sought by biotech competitors without calling into question the drugmarker's commitment to strong patents on their core products …."[603] A lot of gene databases may be considered examples of PPIs.[604] One example is the SNP Consortium, a database of single nucleotide polymorphisms (SNPs), which are changes in a single letter of the genetic code.[605] Because the patenting of SNPs may have the potency of creating anticommons property as far as diagnostic tools are concerned, pharmaceutical companies decided to create a forty-five million dollar, public database containing approximately two million SNPs.[606] What is worth mentioning however is the fact that this ar-

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595 *Cf. id.*
596 Walsh et al., *Working …*, *supra* note 415, at 1021.
597 *Id.*
598 *See* HELLER, *supra* note 120, at 74.
599 *Id.* at 70-72.
600 *Id.* at 70.
601 WILLIAM SHAKESPEARE, HAMLET, Act 2, scene 2, 205–206.
602 HELLER, *supra* note 120, at 71 ("If, for example, they can ensure that raw genetic sequences are unpatentable, then products that build on sequence data are easier to create and become more valuable.").
603 *Id.*
604 *Id.* at 71-72 (naming as examples such databases as Blueprint Worldwide, Protein Data Bank, GenBank, SNP Consortium.).
605 *Id.* at 71.
606 *Id.* at 71-72.

gument[607] is a two-edged-sword. Namely, the actions by the industry may not necessarily be a ramification of the tragedy of the anticommons, but a response in order to battle it.[608]

Another major cooperative solution for the anticommons problem are patent pools.[609] They are a means of assembling intellectual property rights and reducing the costs of bundling those rights.[610] Transaction costs are lowered by lowering the cost of patent mapping, bargaining, and negotiating.[611] They are created through the voluntary actions of market actors and are a means of sharing intellectual property via a program of joint licensing[612] Some patent pools are however recognized by law, e.g. ASCAP, BMI for radio stations.[613] The economic essence of a patent pool is that it "substitutes a regularized transactional mechanism (the pool license) for a property rule that requires individual bargaining for each transaction (negotiation between a single patentee and a potential licensor)."[614]

The disadvantage of patent pools is that they are not a one-size-fits-all solution. Usually they "work best when linked to an emerging technical standard designed to facilitate large-scale technology licensing."[615] For this reason the patent pools for MP3, MPEG-2, 3G platform, or DVD players are considered to have been a great success.[616] Another, and more legal, disadvantage of patent pools is that they run into the danger of being challenged and dissolved on antitrust grounds; such was the fate of the laser-eye-surgery patent pool.[617] Nonetheless issues of public policy are being raised that competition policy concentrates more on preventing anticompetitive practices and not on pro-

[607] This refers to the argument that the creation of a database is proof of an emergence of an anticommons.
[608] *Cf.* Walsh et al., *Working …*, *supra* note 415, at 1021.
[609] *See* Gaulé, *supra* note 298, at 4.
[610] *See id.* at 5.
[611] *Id.* at 5-6.
[612] HELLER, *supra* note 120, at 73; Gilbert, *supra* note 202, at 3. *But see* Gaulé, *supra* note 298, at 2 (highlighting that when defining a patent pool some have in mind a compulsory mechanism that would strike a different balance between rewarding inventors and ensuring access).
[613] HELLER, *supra* note 120, at 72; Gilbert, *supra* note 202, at 6 ("The U.S. Department of Justices has expressly recognized the potential precompetitive benefits of patent pools.").
[614] Gilbert, *supra* note 202, at 3.
[615] HELLER, *supra* note 120, at 73; *see also* Gaulé, *supra* note 298, at 3 ("[T]he modern patent pool has so far been an institution closely linked to a technical standard and designed to facilitate technology licensing on a large scale.").
[616] HELLER, *supra* note 120, at 73; Gilbert, *supra* note 202, at 5; *see also* DU VALL, *supra* note 310, at 337; Gaulé, *supra* note 298, at 2-3.
[617] HELLER, *supra* note 120, at 73.

moting socially beneficial pools.[618] This breeds uncertainty as to biotechnological patents, because patent pools need to assemble essential complementary patents.[619] It is uncertain whether this could be established in the context of biotechnological patents.[620] Moreover, there seems to be less willingness in the industry to create patent pools, because patents are said to matter in a stronger fashion in the pharmaceutical industry.[621] This is due to the fact that the lack of substitutes gives powerful leverage.[622] For this reason a company is often worth as much as its intellectual property is, which often fosters a "bunker mentality."[623]

Thus scholars raise that it is essential to distinguish good patent pools from the bad ones.[624] What is the distinction? It is competition:

> Competition creates benefits when products or technologies are substitutes for each other …. A patent pool can anticompetitive if it inhibits competition between substitutable patented technologies or products made or sold by firms that participate in the pool, or if the pool issues licenses that restrain competition downstream between substitute products that use the pool's technology and other products. A patent pool also may harm competition if it issues portfolio licenses that foreclose competition from alternative technologies.[625]

The procompetitive result is also recognized by the U.S. government, the Department of Justice and the Federal Trade Commission to be exact, in the 1995 Antitrust Guidelines for the Licensing of Intellectual Property (U.S. Guidelines); as the document recognizes that "[t]hese arrangements may provide procompetitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions, and avoiding costly infringement litigation. By promoting the dissemination of technology, cross-licensing and pooling arrangements are often procompetitive."[626] The procompetitive result may be achieved by pools assembling complementary technolo-

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[618] *See* Gilbert, *supra* note 202, at 3 ("Competition policy toward patent pools has focused on the prevention of anticompetitive practices by patent pool members – individually or collectively through the licensing policies of the pool – and has generally paid little attention to the question of how to encourage the formation and stability of patent pools that benefit consumers.").
[619] HELLER, *supra* note 120, at 73.
[620] *Id.*
[621] *Id.* at 74.
[622] *Id.*
[623] *Id.* (*referring to* FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION, chap. 3, 28n174).
[624] *Cf.* Gilbert, *supra* note 202.
[625] *Id.* at 6.
[626] Antitrust Guidelines for the Licensing of Intellectual Property, §5.5 (Dep't of Justice & F.T.C. April 6, 1995), *available at* http://www.justice.gov/atr/public/guidelines/0558.htm#t55 (last visited 2 August 2011) [hereinafter U.S. Guidelines]; *see also* DU VALL, *supra* note 310, at 336-337.

gies.[627] Technologies are complementary "if an increase in the price of one of them reduces the demand for the other."[628] Thus in the case of patents, for complementary ones to exist, one cannot create the end-product without the other.[629]

The European approach is very similar. The 2004 E.U. Guidelines on the application of Article 81 of the EC Treaty[630] to technology transfer agreements recognizes that patent pools may have negative ramifications on competition.[631] They do however also recognize the positive aspects of patent pools:

> §214. Technology pools can also produce pro-competitive effects, in particular by reducing transaction costs and by setting a limit on cumulative royalties to avoid double marginalisation. The creation of a pool allows for one-stop licensing of the technologies covered by the pool. This is particularly important in sectors where intellectual property rights are

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627 U.S. Guidelines, *supra* note 612, §5.5.; *see also* Gilbert, *supra* note 202, at 7.

628 Gilbert, *supra* note 202, at 7.

629 *Id.* ("Two or more patents, each of which is essential to make or use a technology, are complements because no one patent is useful without access to the others.").

630 Consolidated Version of the Treaty on the Functioning of the European Union art. 101, Sep. 5, 2008, 2008 O.J. (C115) 47.
("1. The following shall be prohibited as incompatible with the internal market: all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market, and in particular those which:
(a) directly or indirectly fix purchase or selling prices or any other trading conditions;
(b) limit or control production, markets, technical development, or investment;
(c) share markets or sources of supply;
(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;
(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts
....
3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:
— any agreement or category of agreements between undertakings,
— any decision or category of decisions by associations of undertakings,
— any concerted practice or category of concerted practices,
which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which does not:
(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;
(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question.").

631 Commission Notice 27/04/2004, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements, §213, 2004 O.J. (C 101) ("Technology pools may be restrictive of competition. The creation of a technology pool necessarily implies joint selling of the pooled technologies, which in the case of pools composed solely or predominantly of substitute technologies amounts to a price fixing cartel. Moreover …, technology pools may also,… result in a reduction of innovation by foreclosing alternative technologies. The existence of the standard and the related technology pool may make it more difficult for new and improved technologies to enter the market."); *see also* Gaulé, *supra* note 298, at 7.

> prevalent and where in order to operate on the market licences need to be obtained from a significant number of licensors. In cases where licensees receive on-going services concerning the application of the licensed technology, joint licensing and servicing can lead to further cost reductions.[632]

The Guidelines further explain what constitutes and what prerequisites such a positive patent pool should fulfill. Namely, the technologies in the patent pool cannot include substitute technologies.[633] Concordantly this means that the technologies in the pool need to be essential. [634] This is considered to have a precompetitive result.[635] The Guidelines state that an essential technology is:

> … opposed to non-essential if there are no substitutes for that technology inside or outside the pool and the technology in question constitutes a necessary part of the package of technologies for the purposes of producing the product(s) or carrying out the process(es) to which the pool relates. A technology for which there are no substitutes, remains essential as long as the technology is covered by at least one valid intellectual property right. Technologies that are essential are by necessity also complements.[636]

A patent pool that contains complementary but non-essential technologies may be, on the other hand, considered as anticompetitive.[637] Moreover, if the pool has a dominant position on the market, royalties and other licensing terms should be fair and non-discriminatory and licenses should be non-exclusive.[638] Finally, licensors must be free to develop competing products and to grant licenses to entities outside the pool.[639]

To sum up, market-driven solutions place a lot of trust in market actors. Concordantly, these solutions place a lot of trust in the reasonability axiom. Those who do not entirely trust market entities propose that the government should step in. This leads t various regulatory solutions.

3. LEGISLATIVE AND GOVERNMENTAL SOLUTIONS

[632] Commission Notice 27/04/2004, §214, 2004 O.J. (C 101) [hereinafter E.U. Guidelines].
[633] *Id.* §§216, 219 (stating that two technologies are substitutes when either technology allows the holder to produce the product or carry out the process to which the technologies relate. And explaining further that the inclusion in the pool of substitute technologies restricts inter-technology competition and amounts to collective bundling.).
[634] *Id.* §216.
[635] *Id.* §220.
[636] *Id.* §216.
[637] *Id.* §221.
[638] *Id.* §226.
[639] *Id.* §227.

Regulatory solutions are the subject of much debate, because they breed opposition from pharmaceutical companies, who fear the change in the patent system may weaken the patents for their downstream products.[640]

A major proposal, especially in the U.S., for tweaking the patent system is to introduce a research, experimental, and diagnostic use exemption.[641] Indeed, as part of the Hatch-Waxman Act,[642] a research exemption was incorporated into the United States' patent laws.[643] §271(e)(1) of the U.S. Patent Act provides such a research exemption:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or important into the United States a patented invention…solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.[644]

The famous case of *Madey v. Duke*[645] seems ended the research exemption debate. The U.S. Court of Appeals for the Federal Circuit disabused universities and nonprofit organizations of any notion of special status by deciding that:

> Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.[646]

Although it was possible for the U.S. Supreme Court to clarify the research exemption issue, it missed this opportunity.[647] In the case of *Life Sciences v. Merck KgaA*,[648] the U.S. Supreme Court held that the exemption "extends to all uses of patented inventions that are reasonably related to the development and submission of any in-

640 HELLER, *supra* note 120, at 75.
641 *See id.*
642 The Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), Publ. L. No. 98-417, 21 U.S.C. 505.
643 Li, *supra* note 48, at 366.
644 Patent Act, *supra* note 284, § 271.
645 *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002).
646 *Id.* at 1362.
647 Kevin Noonan, *Merck KGaA v. Integra Lifesciences I, Ltd. (2005)*, *in* PATENT DOCS: BIOTECH & PHARMA PATENT LAW & NEWS BLOG, Oct. 27, 2006, *available at* http://patentdocs.typepad.com/patent_docs/2006/10/merck_v_integra.html
648 *Merck KGaA, Petitioner v. Integra Lifesciences I, Ltd., et al, 545 U.S. 193 (2005)*.

formation under the Food, Drug and Cosmetic Act],"[649] thus not favoring any of the parties to the dispute.[650] Nevertheless, as mentioned earlier, the research exemption should in principle apply to research tools, as their very name suggests that their very purpose is research.[651]

Another proposal is to change certain provisions in the patent laws. One such proposal is to expand the exclusion to what constitutes patentable subject matter.[652] An additional beneficial change may be to shorten patent protection for a gene to five years.[653] Such a solution however is criticized as unworkable, as it would fall under the "nondiscrimination" clause under TRIPS, which states that "patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."[654]

Proponents of changing the patent laws in the U.S. raise that public order or morality clauses should be added to the patent laws.[655] With this proposition is connected the notion of heightening judicial scrutiny of legislative delegation to private interests, or simply towards regulatory givings, in order to enable courts to prevent anticommons property from forming.[656]

U.S. laws can also be changed by extending the reach of NIH licensing guidelines.[657] This would include providing for a research exemption to all federally funded research.[658] Such notions relate to strengthening the government's march-in rights, or even empowering the NIH to terminate patent rights to prevent anticommons property from forming.[659]

There are also changes which could be made to the patent administration, like increasing the number of patent examiners.[660] Additionally, it is raised that patent examinations concerning human DNA should be strengthened.[661] The same could be applied

[649] *Id.* at 203.
[650] Noonan, *supra* note 639.
[651] *See* DU VALL, *supra* note 310, at 261.
[652] *See* HELLER, *supra* note 120, at 75.
[653] Li, *supra* note 48, at 366 (*referring to* Courtney J. Miller, *Patent Law and Human Genomics*, 26 Cap. U. L. Rev. 893, 921 (1997).
[654] Li, *supra* note 48, at 366; TRIPS, *supra* note 320, art. 27(1).
[655] *See* HELLER, *supra* note 120, at 75.
[656] Dibadj, *supra* note 14, at 1117.
[657] *See* HELLER, *supra* note 120, at 75.
[658] *Id.*
[659] *See id.* at 76.
[660] *See id.* at 75.
[661] Li, *supra* note 48, at 367.

by the examiners to prevent patent claims from being too broad.[662] Indeed, already thirty eight percent of the patent claims filed fail to meet one or more legal requirements to be patentable.[663] An interesting suggestion by Michael Heller includes the "creation of an office within the PTO responsible for studying the effects of the patent regime on competition and innovation – an internal institutional counterweight to the staff's pro-patent bias."[664] There exists also the notion for the USPTO to "revamp financial incentives to promote decisions based on the quality of patents rather than their quantity."[665]

There are also other, more original notions, touching upon the issue of preventing anticommons property from forming. Among these is the idea to revitalize certain substantive law, or rather common law, doctrines, which includes reshaping the public interest standard into a consumer welfare standard.[666] The latter standard brings with it a strengthening of competition by protecting "new entrants against established interests who currently use givings to squelch competition under the 'public interest' banner … A consumer welfare standard will force incumbents to confront what they hate. It pushes regulation to combat bottleneck control."[667] By a shift from a pure efficiency standard and focusing more on the consumer, regulations would be created that debunk the arguments used to perpetuate an anticommons regime.[668]

Another proposition is the so called public trust concept.[669] The notion dates back to the times of Justinian and it stood for the idea that certain resources like fish, wild animals, and river should never be privately owned – these were called *res extra commercium* or *res communes*.[670] It was also recognized by U.S. law in the case of *Arnold v. Mundy*.[671] In that case the defendant took oysters from the bed, which was claimed by the plaintiff.[672] In deciding the case, Chief Justice Kirpatrick stated:

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662 *See* Paradise et al., *supra* note 375, at 1567 ("As with any new technology, the USPTO must have competent patent examiners to guarantee that patents are not issued that are overly broad or overarching.").
663 Li, *supra* note 48, at 367 (*referring to* Paradise et al., *supra* note 375).
664 HELLER, *supra* note 120, at 76; *see also* Paradise et al., *supra* note 375, at 1567 ("Some have even argued that applications should be reviewed by the USPTO with different levels of scrutiny, depending on how much social cost they entail.").
665 Paradise et al., *supra* note 375, at 1567.
666 Dibadj, *supra* note 14, at 1105.
667 *Id.* at 1106.
668 *See id.* ("Such an approach would quickly debunk arguments supporting regulations that perpetuate an anticommons.").
669 *Id.* at 1107-1110.
670 *Id.* at 1107 (*referring to* Gerald Torres, Who Owns the Sky?, 19 Pace Envtl. L. Rev. 515, 5530 (2002)).
671 *Arnold v. Mundy*, 6 N.J.L. 1 (1821).
672 *Id.* at 9-10.

> [T]his power, which may be thus exercised by the sovereignty of the state, is nothing more than what is called the jus regium, the right of regulating, improving, and securing for the common benefit of every individual citizen. The sovereign power itself, therefore, cannot, consistently with the principles of the law of nature and the constitution of a well ordered society, make a direct and absolute grant of the waters of the state, divesting all the citizens of their common right. It would be a grievance which never could be long borne by a free people.[673]

In other words, the idea is to entrust the management of scarce resources to the state and protect the public from destabilizing changes to those resources.[674] The goal of the public trust concept is to curtail the state's ability to perpetuate givings, by making it the custodian of certain public assets.[675]

The public trust concept, it is argued, fits well with the notion to increase the frequency of using liability rules rather than property rules.[676] In a liability regime one can infringe on someone's rights, if one is able to pay the price.[677] Therefore, one cannot be stopped from the infringement, but only discouraged. What is more important however is that weak entitlements, i.e. those protected through a liability regime, may prove to efficiently facilitate trade.[678] This seems to be superior to a property regime, since in a property regime the one who is entitled can entirely prevent the infringer from infringement, thus creating an anticommons.[679] In a liability regime on the other hand, the state sets the price.[680] This can be illustrated more clearly on an example:

> Conceptualize, for example, a number of rights vested collectively in citizens: the right to enjoy clean air or vibrant forests, for example. Under a property rule regime, corporations who want to infringe on those rights would need to bargain with the polity at large. Of course, this is virtually

673 *Id.* 78.
674 Dibadj, *supra* note 14, at 1108 (*quoting* Joseph L. Sax, Liberating the Public Trust Doctrine from Its Historical Shackles, 14 U.C. Davies L. Rev., 185, 188 (1980) ("The central idea of the public trust is preventing the destabilizing disappointment of expectations held in common but without formal recognition such as title. The function of the public trust as legal doctrine is to protect such public expectations against destabilizing changes, just as we protect conventional private property from such changes.").
675 *Id.* at 1109 ("If the regulatory state is viewed as the custodian of the public assets–rather than merely as protecting some ill-defined 'public interest'-then its ability to perpetuate givings is sharply curtailed.").
676 *Id.* at 1113, 1141.
677 *Id.* at 1113.
678 *Id.* (*quoting* Ian Ayers & Eric Talley, *Solomonic Bargaining: Dividing a Legal Entitlement to Facilitate Coasean Trade*, 104 Yale L.J. 1027, 1101-1102 (1995)).
679 *Id.* at 1114.
680 *Id.* at 1114-1115 ([W]ith a liability rule, the entitlement owner is forced to reveal what the entitlement is worth to her, thereby sharply curtailing strategic bargaining and holdouts. [FN394] A hold-up, of course, is the telltale sign of an anticommons.").

> impossible. The corporation could bargain directly with the state to cede those rights (which is happening today), but the state is not in a position to give the rights away, because they belong to the people. Liability rules, on the other hand, would force the corporation to pay for infringement.[681]

In light of this, an area in patent law, which may be worth further looking into is the area of compulsory licenses. Ordinarily, a compulsory license may be granted if TRIPS provides for certain prerequisites to be fulfilled in order to obtain a compulsory license.

> Article 31
> Other Use Without Authorization of the Right Holder
> Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
> …
> (l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:
> (i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;
> (ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and
> (iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.[682]

It has been argued that a compulsory license system should be created.[683] Although a tweaking of the patent system to include a statutory compulsory license may seem to be a good idea, it may nevertheless may prove to be a more costly solution than, e.g. a fair use doctrine.[684] The reason for this is that a case-by-case approach, i.e. through litigation is not cheap.[685]

In summary, it is doubtful that if one wants to find a solution to the tragedy of the anticommons, one has to apply a bifurcated approach of choosing between market-driven solutions or legislative solutions. If society, indeed encounters the tragedy of the anticommons, then it will undoubtedly battle it by taking a little bit from every basket, thus getting the besto of both worlds.

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[681] *Id.* at 1114.
[682] TRIPS, *supra* note 320, art. 31.
[683] *See* Paradise et al., *supra* note 375, at 1567.
[684] Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 Colum. L. Rev. 1177, 1242 (2000).
[685] *Id.*

CONCLUSION

The most challenging task in academic writing seems to be to write a constructive conclusion. In the context of the tragedy of the anticommons it is even more difficult, because it is even hard to state for sure whether the problem indeed exists in the context of biotechnology. The journey in this thesis took me from the Native American hunting grounds, which represented the tragedy of the commons, to Moscow kiosks, which illustrated the tragedy of the anticommons. Despite the fact that nothing can be said for certain in this context, I believe that the only constructive statement, which can be said today is that time will tell.

I wish therefore, at the very end conclude similarly, as I have begun this thesis, i.e. with a quotation from the excellent British writer, David Lodge. What is notable in his writing is that the main theme of his books usually revolved around academia – with a very critical undertone. And it seems to me that the subsequent quotation illustrates the debate over the tragedy of the anticommons in a very humorous manner. This is due to the fact that a lot of scholars simply said "I wish to raise that …." The real problem however occurred when thinking about the answers to the question. Therefore, without further ado:

> As is perhaps obvious, Morris Zapp had no great esteem for his fellow-labourers in the vineyards of literature. They seemed to him vague, fickle, irresponsible creatures, who wallowed in relativism like hippopotami in mud, with their nostrils barely protruding into the air of common-sense. They happily tolerated the existence of opinions contrary to their own — they even, for God's sake, sometimes changed their minds. Their pathetic attempts at profundity were qualified out of existence and largely interrogative in mode. They liked to begin a paper with some formula like, 'I want to raise some questions about so-and-so', and seemed to think they had done their intellectual duty by merely raising them. This manoeuvre drove Morris Zapp insane. Any damn fool, he maintained, could think of questions; it was answers that separated the men from the boys.[686]

[686] DAVID LODGE, CHANGING PLACES: A TALE OF TWO CAMPUSES 35-36 (London: Secker and Warburg, 1975).

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