Biotechnology under the European patent regime with regard to science and industry

Dr. Marc Dressler
Rotterdam, 17 June 2010

Table of contents

1 Intellectual property rights in a theoretical perspective

When Erasmus of Rotterdam published in 1503 the Adagia, he considered the list of proverbs and memorable sayings of the ancient world as cultural heritage of mankind. The accumulated wealth of classical antiquity in the little book providing guidance in life was thus destined for common use. With help of the printing press Erasmus intended the appropriation of the inherited wisdom by a large number of people, deploring that the wisdom had hitherto been the intellectual property of only very few people.[1]

With these few remarks Erasmus provides the basic concepts for a critical analysis of intellectual property rights which shall be adopted and further developed in the present work. Replacing antique wisdom by modern knowledge the purpose of common use persists. The purpose indicates origin and destination of knowledge: it is gathered from common experience and applied in pursuance of social aims. In this public interaction with regard to knowledge, its appropriation gets the meaning of learning. While reading what others have found out we learn something. The book in our hands is what we possess or may own, but not what we have learnt from the book. Intellectual property is property in a product like books. Printing presses finally facilitated the distribution of appropriable products.

The intellectual property of interest here are patents, in particular European patents. Patents go in one important point beyond Erasmus: Additional to the ownership of a product, patents bestow their proprietors with the privilege to exclude others from reproducing a product, and therewith to deprive it from common use. The enforcement of that privilege might thus have detrimental consequences for society when restricted common use abates the legacy inheritable by future generations. Therefore, the following pages shall shed some light on the opportunities and threats entailed in the European patent regime. I will do so by investigating the potential effects of the regime on industry and science in the field of biotechnology.

To this end I will largely follow a critical approach as applied in political science. This means, that I will work outwards, enlarging the frame of reference for patent law so as to bring into view the broader field of societal institutions of which the specific actors and factors involved in patents form a part, instead of working inwards, downsizing the frame of reference so as to focus on a specific issue of patent law.[2] The critical approach of political science seems to me appropriate, because it enables to integrate diverse disciplines from which I have to borrow for my criticism. I will resort to insights of analytical philosophy with regard to rule following when encircling the meaning of knowledge; I will resort to results of sociology of science when determining the rules and norms of science, and actual practice in science; I will resort to international law when presenting the European patent regime and when analyzing EU legislation; and I will resort to the perspective of institutional economics when exploring the role of patents in the innovation process against the background of interdependencies between university and industry.

The opportunities and threats for science and industry implied in European patent law will be delimited by the respective policy aims of the EU. Within the political framework actors and factors will be identified and analyzed that determine the effectiveness of the patent regime. The applied standard for assessing the effectiveness will be de- and refined out of the European Commission's policy papers: strengthened competitiveness of the internal market in general; enhanced investments in research and development of new technologies, and facilit-

1 Eden (2001), p.4.
2 Cox (1981), p.129.

ated and accelerated dissemination of research results in particular. The emphasis of the critical analysis will be on biotechnology, because biotechnology is knowledge intensive and investment intensive: access to research results and venture capital is vital for biotechnology.

The policy of the EU is framed in terms of knowledge economy which is about the capitalisation of knowledge that implies appropriating scientific research results to generate income.[3] Knowledge economy thus requires knowledge generation or innovation, commodification of knowledge as a product, appropriation of that product, and proprietary protection of it. Before elaborating in detail the policy aims, a conceptual clarification of 'knowledge' with regard to what actually is appropriable in terms of knowledge seems to me necessary. For that reason I will begin chapter one arguing that knowledge is related to skills that adhere to and are dependent on the public life of a society which per se is not appropriable. To extend the meaning of 'knowledge' to appropriable products, which can be protected by patent rights, requires therefore some efforts. Such efforts should only succeed when reasonably justified. The justification then is given by EU's knowledge policy. In light and terms of this policy science will be portrayed. The portray pictures the normative ideals of science in contrast to the actual motivation of scientists and therewith sketches potential gateways through which science might be affected by patent rights.

The second chapter will expose European patent law and give a comprehensive analysis of Directive 98/44 on the legal protection of biotechnological inventions. The Directive is taken as legal transposition of the EU's knowledge policy. Basically, it subjects biological material to the same mechanisms of patent law as any other invention, and provides even facilitations with regard to patentability. In sum, the Biotech Directive facilitates the commercialisation of biotechnology through a) expansion of patentable objects' scope to objects occurring in nature, therewith blurring the difference between invention and discovery; b) integration of plant varieties into the scope of patentable objects; c) deposition of material in place of the stricter disclosure requirement of verbalized explanation; and d) expansion of protection to objects derived from patented biological material.

Based on the preparatory work on knowledge in the philosophical section, the person skilled in the art will be accentuated in the analysis of the granting procedure of a European patent. Examining a patent application it is essentially the knowledge attributed to this person that is decisive for the grant of a patent with regard to prior art and technological progress incorporated in an invention – the so-called inventive step. The skilled person conceived as a legal fiction emphasises the envisaged neutrality of the procedure; it shall not insinuate that the construed person be without social background.[4] Rather, its fictitious localisation in the scientific context shall effectuate a counterbalance to the primarily private interests motivating a patent application. The scientific context then informs patent law in double respects: the interpretation of European patent law *and* further legal harmonisation of European patent law depend essentially on scientific and technological progress. Without such progress adjudication concerning for example the developmental stages of a human embryo becomes impossible.

The effective contribution of patents to the commercialisation of biotechnology will be discussed in chapter three. There I will explore to what extent patents can be integrated in the economics of innovation, probing the two prevalent economic doctrines, namely the provision of a temporary monopoly and the protection against free-riders. The search for reliable indic-

[3] Etzkowitz (1997), p.141.
[4] Dewey (1925), p.670.

ators substantiating patents' effects on innovating activities, and the consultation of studies employing these indicators will show that along with the market of inventions a market of patents has been established generating value for patent holders independently of the patented inventions: Companies frequently use patents to retain market share without being innovative. Litigation fees for infringement procedures become a considerable item of a company's balance sheet that are deployed to deter innovative competitors from entering the market. A comprehensive theory of patent economics would have to take into account such abuse of patents on patent markets, as well as alternative tools companies use to recoup returns on their inventions. From the elementary observations of economics it seems that the market of patents grows at the cost of the market of inventions. In any case, investments in patents are not necessarily investments in innovations.

For these reasons patents are a weak indicator of innovation. The lack of reliable indicators for innovation aggravates an assessment of knowledge dissemination through patents which is the object of chapter four. As a proxy for knowledge dissemination disseminative activities like publishing and sharing of research tools or materials will be explored. I will therefore assume that any hindrance of these disseminative activities will result in a reduced dissemination of knowledge. In other words, hindering effects of patents on science will affect knowledge dissemination negatively. The determination of these effects is supported by a look at the affiliation of science with industry. I will argue that the entanglement of universities in networks of 21st century knowledge economy reinforces the effects of the European patent regime on academic science. Contractual obligations with companies supplant any remained norms and virtues of sharing and free exchange expressed in the codes of conduct of science, and make scientists even more cautious and reluctant to disseminate their research results.

The fifth chapter finally suggests that patents are with regard to the aims of the EU's knowledge policy more a threat than an opportunity. Their identified effects on industry are predominantly negative, and therewith the effects on – the entangled – science, too.

1.1 Knowledge as a product

Nobody knows what knowledge is, but everybody knows something. Some know how to sequence genes, some know the location of the European Molecular Biology Laboratory, and others know a lot about patent law. We are more familiar with knowing than with knowledge; the verb is more meaningful to us than the noun. This indicates that the meaning of knowing is basic, and the meaning of knowledge borrows from the meaning of knowing. People who know something are proficient; they can demonstrate their proficiency. They are for example able to conduct experiments, to answer queries, or to give explanations and references. In other words, knowing people are skilled persons. Hence, the term 'knowledge' refers to a skill, a capacity of people.[5]

The capacity is exercised in interaction with other persons. Others question our skills, doubt our claims, and demand some evidence we then have to demonstrate. The demonstration is decisive for our skill to be approved as knowledge. No one can determine knowledge on his own. It requires other people to check the skills: they analyze and rank our performance; they confirm it or refute it. Knowledge claims have to pass a review, be it by peers or by a wider audience.[6] Even in case of simple discoveries it needs third parties to ascertain whether the

[5] Stehr (2000), p.211.
[6] Kitcher (2001), p.39.

discovery is a discovery. Knowledge thus is constituted in social cooperation. In this sense knowledge is public. And in this sense it retains its public nature when someone exercises her capacities in privacy.

Since everybody knows something we cannot but know. Knowledge forms an integral part of people interacting in society. In this social interaction men not only demonstrate their skills, but they also improve them and develop even new skills. Or in terms of knowing: they teach, learn and invent. This teaching, learning and inventing is identified with the progress of knowledge. The progress in turn hinges on the skills of people with different biographies in different societies, and both the people and the societies change over time. Thus, knowledge is tied to the life of people in evolving social settings. In these settings the standards for attributing knowledge shift depending on how far people are able to develop their capacities in their lives. This inherent evolution of knowledge together with its public nature might be referred to as public life.

The public life of knowledge underscores the evolutionary character of knowing owed to the steady and unavoidable interaction of living beings with their environment, and in particular with each other. Knowledge follows the stony track of trial and error when developing a skill under public guidance and criticism. Theories survive as long as people are capable of applying them successfully, that is in a socially approved manner. Knowledge is embodied in skilled people – and dies with them.[7] To know means to convince others by one's performance throughout lifetime. Therefore, knowledge is a skill with a life in public.

Nevertheless, knowledge might be given different meanings. In a first step, this is quite easy. We simply have to take the noun and define it through certain attributes. This is much harder for verbs which are usually defined in their nominalized form. However, with nouns too, the introduction of a new or derivative meaning requires some efforts. This is because a definition of a term has to convince the people who shall use the term accordingly. In the context of knowledge no one would integrate an aberrant use of 'knowledge' into its public life without good reasons. Certainly, the grammatical move that the noun suggests a signified entity behind it would not be reason enough to convert the skill into a product.

The products behind knowledge are texts, hypertexts, tables, diagrams, computer programmes and the like. These products cover theories, hypotheses, proofs, discoveries, inventions, discussions and so on. They adequately represent the public life that is going on in knowledge generation. We use these products to teach and learn, and we produce these products to demonstrate our skills. Thus, they testify the interactive character and public nature of knowledge. But these products are no knowledge. Rather, their reading, using or understanding requires a certain level of skills. The scholarly output thus is precondition and result of knowledge, not yet knowledge itself.[8] Companies study journals and other publications to enhance their absorptive capacity,[9] i.e. employees train their skills to a level that allows them to exploit knowledge developed outside the company. Therefore, a clear distinction between skills and the products produced by skilled persons is appropriate. Any such product might then be referred to as knowledge product.

Usually knowledge products are assembled in journals, books or databases, and materialized on paper or electronically on compact or hard disks. Most of these knowledge products are

7 Machlup (1980), p.167.
8 Knorr-Cetina (1981), p.94.
9 Cohen (1990), p.133.

delivered by publishing companies and are thus implicitly goods on the market. Knowledge products however are not only available on the market. Libraries, archives and the internet give public access to journals, books, diaries, manuscripts or databases. These institutions are publicly owned but privately enjoyed, and thus are referred to as the knowledge commons.[10]

Patents, too, qualify for knowledge products; namely the invention and the document. Thus, a biochip or microarray is a knowledge product as well as its specification in the patent description. Both are achieved by skilled persons. The patent document certifies publicly the knowledge claim for the invention laid down in the patent application.

To all knowledge products I will refer to as public products because the economics of public goods does not apply to knowledge or knowledge products. First, knowledge is no good or commodity. To know something does not entail the possession and entertainment of intangible and nonetheless commodifiable or otherwise separable ideas; it does not even require the possession of knowledge products. Knowledge is a skill, however valuable for economy. Knowledge is embodied in persons, and incorporated in inventions – which is a knowledge product.

A knowledge product might be any good.[11] It might be rivalrous or non-rivalrous,[12] excludable or non-excludable. Genetically modified rice for example is as rivalrous as its wild-type variety: the consumption of the invented rice reduces the availability of it for other consumers. Technologies or research tools on the other hand might be non-rivalrous. The use of a method for cloning antibodies by one company does not preclude its use by another company. And without patent rights the other company could not be excluded from doing so. The patent document, like other publications, must be seen as rivalrous because it is tied to a medium. The medium might hardly wear out when in use, and copying it might be almost costless, it still remains rivalrous. In return it is appropriable.

1.2 Knowledge as property

The appropriation of a public product requires a bundle of measures that stipulate for example which public products should be privatized and to what degree. When adopting such measures one has to consider that appropriating a privatized public product might chisel a vital element of knowledge's public life. This life flourishes with the free and open access of people to all sorts of knowledge products. An invention must leave the laboratory, be inspected by critics, and convince users of its utility. While studying, testing and using the invention people not only widen their learnt horizon, but they generate as well new knowledge which leads to new knowledge products: improvements of the invention or inventions that build on it, supplement it, or replace it.

The public life of knowledge entails a biography of knowledge products. Each knowledge product has its own history, a history entangled with intellectual struggle, gift and chance, cooperation and intrigue. Knowledge products not only have parents, but also predecessors: the skilled persons who create a knowledge product rely on a knowledge they have gained from studying prior knowledge products. Present knowledge products owe their existence not only to their producers, but also to past knowledge products. Each knowledge product hinges

[10] Ostrom (2007), p.46.
[11] Jaffe (2002), p.200.
[12] Samuelson (1954), p.387.

on another, like the knowledge of one person depends on that of another. A complete biography of knowledge products would reveal all their organic ramifications, all the personal and institutional interdependencies. Briefly, an uncountable many, people already dead or still alive, contribute directly or indirectly to any creation of knowledge products.

No single person ever creates a knowledge product alone – isolated from other persons and their knowledge without having recourse to past knowledge products. It is the public life of knowledge that gives birth to knowledge products. Or in other, more profane, words: what one person has invented would have come into existence anyhow sooner or later.[13] Indeed rather sooner than later, what the frequent occurrence of simultaneous discoveries demonstrates.[14] To name only some of the most important: oxygen (Priestley and Scheele), electromagnetic induction (Henry and Faraday), natural selection of species (Darwin and Wallace), geminate chromosomes (Boveri and Sutton), gene sequencing (Gilbert and Sanger), or giant magnetoresistance (Fert and Grünberg); and so are thermometer (Galileo and Santorio), telescope (Lipershey and Janssen), typewriter (Sholes and Hansen), light bulb (DeMoleyns and Starr), steamboat (Fitch and Fulton), camera (Talbot and Daguerre), telephone (Bell and Reis), car (Marcus, Benz and Daimler), television (Farnsworth and Zworykin), or microchip (Kilby and Noyce). Note that the inventions are attributed to people who published their discovery or filed a patent; not any inventor does. And note that all of the given discoveries have been developed further. Their detailed histories, which cannot be reproduced here, show all the successful and shipwrecked contributions of people working in the field; that is they reveal the common efforts embodied in knowledge products.

The common efforts culminate in an individual inventor who contributes the final piece to a complex puzzle. The inventor is the person who finally presents the perfected invention. But clearly, from the presentation of a common achievement no individual property claims are derivable.[15] To give credit to the final inventor for a knowledge product would amount to crediting the last man needed to lift a rock for lifting it.[16] Therefore, the privatization of a public product conceals unjust rewards. Would the final inventor alone be entitled to appropriate the knowledge product, she would be rewarded disproportionately for her efforts compared to all the other contributors. Through appropriation she is rewarded with the value of the whole product, instead of the value emanating from finishing an invention some time. From the evolutionary perspective of public life the inventor deserved only the reward related to the timely benefit of society enjoying the invention already before others would have come up with the same or a similarly useful invention.

The inventor being rewarded with the appropriation of the product need not generate social injustice with regard to other contributors. Many of them are skilled enough to reproduce the finished invention and thus appropriate it for themselves. This however is prevented by patent law. A patent declares an invention the intellectual property of the inventor. And the concomitant intellectual property rights, if the inventor makes use of them, prevent the appropriation of the invention by others. The only legitimate manufacturer of a patented invention is the patent holder. So where is the intellectual property?

First of all it is not property of knowledge. Knowledge is no product that could be appropriated; it represents a personal skill.[17] And even if one admitted that skills can be owned, this

13 Nozick (1974), p.181.
14 Merton (1973), p.352.
15 Kuflik (1989), p.226.
16 Hettinger (1989), p.38; Drahos (1996), p.62.
17 Schmidt (2004), p.765.

knowledge property would be inalienable. Knowledge is an integral part of a person which cannot sensibly be owned by a third party – neither intellectually. Appropriable is a knowledge product only, the manifest invention. Now the knowledge product manufactured by the patent holder is for sure his property. But if the invention (not the patent) is purchased by a customer, then she owns the invention and the holder loses his property in it. The difference between both is that the patent holder may produce a copy of the invention and sell it anew, whereas the customer may not. The intellectual property rights of the patent holder prevent her from doing so. Thus, additional to the property right in a knowledge product intellectual property rights confer to the beneficiary a command over the exercise of other people's knowledge: No one but the patent holder is in principle entitled to use his skills for the exploitation of an invention. A patent allows the individual exploitation of a collectively achieved product. Therefore, intellectual property rights have more of a privilege than of a property right.[18]

The appropriation and privatization of a public product, and the subsequent allocation of privileges is, given the social implications, in need of a political justification; a justification that legitimated intellectual property like patents and showed that their introduction and maintenance is in the public interest.[19] Such a justification starts with a policy outline of the purpose or purposes of patents and the role they shall play in society. Such a knowledge policy[20] reaching out to the public life of knowledge must of course be embedded coherently in a visionary conception of a just society to which intellectual property legislation shall live up to.[21]

1.3 Knowledge policy

The European Commission's vision of a future living together in Europe bears the characteristics of a bio-society.[22] It observes a revolution taking place in biotechnology. [23] New knowledge is generated that offers new applications in healthcare, agriculture and food production, and environmental protection. Gene therapy, biofuels, resistant crops or decontaminating bacteria will very likely shape the society of coming generations, for which reason it seems sensible to expand our knowledge of molecular biology and genetics, i.e. to engage in experiments and the production and distribution of respective papers and articles.

A closer look at the Commission's policy reveals that tomorrow's bio-society is not so much about the expansion of knowledge in biotechnology; to this end it would make equal sense for the European Union to support university departments of biology and biotech dedicated firms in the United States, Japan or elsewhere, and study their papers or buy drugs and fuels from their companies; tomorrow's bio-society is very much about knowledge production in Europe for the sole reason to market the promising applications of biotechnology and generate wealth at home.[24] The aims pursued are thus mainly economic; and it is the economic dimension which makes knowledge a European issue. Without any relation to the internal market the European Union could not legislate on knowledge. The European Union therefore has an

[18] Drahos (1996), p.200; Moore (2003), p.191; Schmidt (2004), p.765.
[19] Steinvorth (2004), p.730.
[20] Drahos (1996), p.223.
[21] Fisher (2000), p.33; Sen (2009), p.25.
[22] European Commission (1980), p.1.
[23] COM (2009) 467, p.11.
[24] Jaffe (2002), p.200; Bains (2009), p.175.

institutional interest in promoting the free movement of knowledge as the fifth freedom in the internal market, apart from the free movement of goods, services, capital and persons.[25]

A still closer, so to say a microscopic look reveals that the policy's primary concern is not only the free movement of knowledge between Member States, but also the free movement of knowledge from laboratories to the marketplace[26]. The Commission states an excellent knowledge capacity in Europe and deplores that notwithstanding its scientific excellence the Union is less successful than other regions of the world at converting its skills into new products and market share.[27] Europe's failure to exploit its knowledge resources and to profit from its excellence in science leads to a diminishing competitiveness of Europe in the high-technology sector on the global market. In order to remain competitive therefore, the European Union has no choice but to become a 'vibrant knowledge economy' and adopt a policy that catalyzes the genesis of new knowledge, its use and commercial exploitation.[28]

The conception of the envisaged knowledge economy[29] for tomorrow's bio-society dates back to yesterday. Thirty years before the birth of the European Communities, economists argued that economic growth is the result of a fundamental economic force: innovation.[30] Innovations embody new knowledge products resulting from new knowledge. They grant a monopolist position to inventors until reverse engineering competitors enter the market and therewith force further innovations to gain again monopoly profits. The source of innovations is knowledge: new knowledge grows out of existing knowledge; we build new skills on existing ones. In particular scientific knowledge became important for technological innovations. Science serves as a 'multiple-purpose knowledge base'[31] for new technologies. Scientific knowledge constitutes a basic determinant of the kinds of innovations which can be undertaken successfully.[32]

The self-energising cycle of knowledge – innovation – growth – knowledge has become a credendum of the Commission. Knowledge creates innovation which is new knowledge, and innovation creates economic growth whose profits are invested to improve the knowledge-base for newer innovations.[33] Much of the scientific knowledge is created at public universities and remains there, whereas it should, according to the Commission, become known to enterprising inventors who transform the knowledge into a marketable good, to persons like Thomas Edison who did not invent the light bulb but made everybody buy one. Thus, the success of Europe's knowledge economy rests upon the generation, diffusion and application of new knowledge.[34] The vital importance of knowledge for companies and economies is acknowledged by the United Nations System of National Accounts which recognized in 2008 research and development as part of capital formation on the basis that research and development activities lead to 'knowledge assets'.[35]

At the core of the European knowledge policy lie predominantly mechanisms to raise higher investments in the knowledge-base, as the sum of all available knowledge products resulting

25 COM (2008) 466, p.3.
26 Elsemore (2009), p.221.
27 COM (1997) 314, p.1.
28 COM (2005) 488, p.3.
29 Drucker (2008), p.72; World Bank (2007), p.9.
30 Schumpeter (1928), p.376.
31 Rosenberg (1974), p.100.
32 Rosenberg (1974), p.105.
33 COM (2009) 467, p.3.
34 COM (2002) 27, p.13.
35 Stiglitz (2009), p.106.

from research and development – in particular private investments. To ask for private investments in public products means to demand a high degree of philanthropy from entrepreneurs and companies. Why should a company invest in a product everybody can cheaply appropriate? And why should it enlarge and improve an excellent capacity of scientific knowledge when its main deficiency putatively is the lack of absorptive capacity to exploit just this knowledge? Investments in absorbing public knowledge products are a risky business for companies because competitors could easily do the same and thus belittle the margin of potential profits. Hence, market competition might not be optimal for knowledge and generate fewer inventions a society would in principle be capable to generate.[36]

The classic approach, also adopted by the European Commission, to the underproduction of knowledge under competitive market conditions is to privatize knowledge, making it intellectual property and providing its originators with patent rights which exclude others from using the resulting knowledge products.[37] Patents shall protect and compensate inventors for their investments such that the knowledge-base is broadened and economic growth strengthened. In this regard a knowledge economy without patent rights would not provide the optimum level of welfare it is capable to provide its participants. Given these welfare prospects, it even has been suggested that intellectual property deserved a stronger protection than bare property.[38] The Commission is satisfied yet with an effective and efficient protection of intellectual property to foster research and innovation.[39]

To be on the forefront of innovation, the Commission deems an improved patent strategy indispensable; a strategy that includes issuing its own European Union Patent – in addition to the European Patent of the European Patent Convention – and establishing a European Patent Court.[40] Both the Union wide grant and enforceability of the European Union Patent aim at an efficient and effective protection of patents in Europe, because companies engaged in knowledge-intensive sectors of high-technology are supposed to make investments if the results of their research is legally protected.[41]

Thus, the Commission expressly justifies the framing of knowledge products as private property. The privilege of patent rights to exclude others from making use of certain knowledge products grants patent holders a monopoly position on the market and therewith – for a period of time – freedom from reverse engineering competitors. In this sense, patent protection shall operate as an incentive to invest in knowledge creation. The justification thus omits the common efforts necessary to achieve innovations and focuses instead solely on the business assets of patents. Patents are important as commodifications of knowledge that make knowledge a tradable good. The policy builds on the conversion of a public need in private demands: the selective condition of enhancing one's capacities in the struggle for life, the steady need of knowledge to master conflicts in society warrants continuously high market prices when converted into a supply and demand mechanism. A demand for knowledge cannot but persist because knowing is an inherent part of life. And it seems politically decided that private suppliers shall profit from this persisting demand for the sake of economic growth.

36 Rosenberg (2004), p.81.
37 Guellec (2007), p.50.
38 Tsioumanis (2003), p.616; Rosenberg (2004), p.90.
39 COM (2005) 488, p.7.
40 COM (2007) 165, p.3.
41 WIPO (2006), 33.25.

In this economic context, patents supplement market forces which do not lead on their own to the optimal level of innovation in society.[42] It is the trade aspect of the incentives to create, innovate and trade which makes intellectual property rights for the Commission a cornerstone of a competitive, wealth-generating knowledge economy.[43] When it states that in today's knowledge economy intellectual property rights are 'vital business assets' that encourage creativity and innovation by ensuring a fair return on investment,[44] the emphasis lays on the return on investment. The fairness refers to the amount invested, and not to the actual knowledge contribution; anyway, a fair return for an innovation other than in terms of capital investment would be hard or impossible to determine and therefore would have to be a return to the public domain.

An ancillary justification for the legal privileges affiliated with patent rights shall be their pro-competitive effects. Knowledge in the form of patents would then be at the same time exempt from competition and ingredient of an even more competitive market. The rationale behind this paradox is a regard to ongoing concentration processes on markets and the dominance of ever fewer participants. In such a market situation limited monopolies as provided by patents might help small and middle sized enterprises to establish themselves against the dominating multinational companies.[45] In this regard patents could lower the barriers to enter a market. The regard however is deficient to the extent that it does not consider how many new enterprises would enter the market and innovate in the absence of patent rights.[46]

Despite the economic predominance of the Commission's knowledge policy it is well aware of other purposes pursuable with patents besides the establishment of incentives for business profits. From these purposes – such as the protection of personal rights, the quality control of inventions or exchange for secrecy[47] – the Commission is mainly concerned with trade secrets. Knowledge after all should not be kept secret; it should be disclosed because open knowledge obviously stimulates the creation of new knowledge: the more people have access to knowledge products and can study them, the more active the innovative process is, and the likelier are new inventions. In particular the development of biotechnology hinges on the disclosure of knowledge in patent publications.[48]

Thus, the example of biotechnology unifies the two purposes of Europe's knowledge policy: First, to reward intellectual efforts and motivate investments in knowledge intensive undertakings; and second, to facilitate the dissemination of intellectual achievements. Patents shall accomplish both purposes by rewarding inventors for the disclosure of their inventions with the privilege of marketing them undisturbed by competitors. Biotechnology seems to require both. It is a highly knowledge intensive sector that would starve if knowledge products were not available; and it is a highly investment intensive sector where the work of highly qualified people and cutting-edge technologies have to be financed over an incalculable time span. For this reason even sceptics of intellectual property rights admit the need of patents in the health sector of biotechnology.[49]

42 Guellec (2007), p.3.
43 COM (2009), p.11.
44 COM (2009), p.3.
45 Kuflik (1989), p.231.
46 Boldrin (2008), p.75.
47 Weil (1989), p.20.
48 COM (2002) 27, p.22.
49 Lessig (2004), p.258.

Patents, it turns out, are and always have been a means to achieve certain purposes but are not purposes in themselves.[50] The purposes followed by the European Union's knowledge policy are linked by way of its constitution to the internal market. The policy aims at a competitive European knowledge economy where patents are the currency.[51] Patents make knowledge tradable, and patents open markets. Some of these markets rush into areas of hitherto non-commercial exchanges between people, where no property existed or not even exchangeable products had been framed. Here, knowing induces the creation of knowledge products, and knowledge products have to be protected with property rights: skills lead to public products lead to intellectual property. Conversely, the knowledge economy seizes the commons of knowledge and thus influences people's knowledge.

Legislation based on the European Union's knowledge policy must therefore strike a balance between the joint effectiveness of a variety of means market participants have at hand to appropriate returns on their investments, and the extent to which the economic growth contributes to the dissemination of knowledge in society rather than capturing wealth from the public life of knowledge.[52] In other words, the legislator must procure both economic growth and scientific growth. The Commission concedes that with an eye on the scientific progress, legislation on intellectual property needs to be monitored very closely. Regular assessments are required to ensure that the patent regime satisfies the needs of companies *and* academic researchers.[53] The assessments shall ensure that patent law not only grants a right providing protection to private inventors as an incentive to innovate and disclose, but also safeguards the freedom to do scientific research, along with a guarantee of fundamental personal rights.[54]

1.4 Organized knowledge: Science

Europe's knowledge policy spreads between the private exploitation of knowledge and the public availability of knowledge products; presumably in order to make the growth of the European knowledge economy sustainable, because one has to make sure that the creative resources do not deplete when exploiting them. The policy aims at enlarging the body of knowledge products through encouragement to invent and to disclose new knowledge; it shall enable inventors to know as much as possible, for the price that they cannot – during a time span of twenty years – make use of some knowledge whose use is the privilege of the lucky ones who were the last in line of the collective invention process. As has been pointed out, the growth of biotechnology is very much dependent on disclosed scientific progress in the field. Biotechnology thus is an excellent touchstone for the European Union's patent regime which represents the legal transposition of its knowledge policy. Therefore, we will have a short look at the science of biotechnology.

Biotechnology means the technical exploitation of living beings and its constituent elements, especially cells. It combines for this purpose different disciplines, such as biochemistry, microbiology, cell biology and mechanical engineering or genetic engineering. Many drugs are produced by way of biotechnological procedures which allow for safer products: human growth hormones can now be applied without the risk of Creutzfeld-Jakob disease,[55] bleeders can be treated with unlimited sources of coagulation factors free from HIV and hepatitis C

50 Beer (2008), p.114.
51 Guellec (2007), p.11.
52 Winter (1989), p.45.
53 COM (2002) 27, p.22.
54 Overwalle (2009), p.422.
55 Owen (1997), p.46.

virus;[56] and they allow for a cheaper production: the manufacturing of vital substances, such as human insulin or vaccines against hepatitis B and rabies is now fully automated.[57] And they allow for specific diagnostics and therapies of genetic diseases. [58]

Outside of the pharmaceutical sector biotechnology is applied in the chemical industry and the production of foodstuff. It provides yield increases in agriculture making economic plants resistant against vermin and drought.[59] Finally biotechnological procedures solve environmental issues, such as land reclamation[60] or sewage purification.[61] Particularly in the chemical industry biotechnology opens enormous economic opportunities. And indeed, the turnover of listed biotech dedicated firms already doubled between 1998 and 2002, and the number of employed persons at these firms even tripled in the same period.[62] For these reasons the Commission identifies biotechnology with the 'next wave' of knowledge economy;[63] and the Council reinforces the growing economic importance of biotechnology through resolutions like the one that at least ten percent of vehicle fuel shall consist of biofuels by 2020.[64]

Given the opportunities of biotechnology for Europe, the European Union started to legislate on biotechnological issues in 1990. The European Union's regulation currently governs safety requirements for the use of genetically modified objects in laboratories, the release in the environment and marketing of genetically modified objects in food, feeds and seeds, and the patenting of biotechnological inventions[65] and therewith the legal protection of new knowledge from a bundle of disciplines for commercial purposes. Biotechnological inventions are generally classified in processes for the creation or modification of living beings, the results of such processes, and the use of such results.[66]

The broad spectrum of biotechnological inventions immediately raises questions concerning the impact, protective measures to the benefit of private persons have on the public life of knowledge, in particular with regard to the work of scientists. Are patents promoting or impairing the dissemination of knowledge? Is disclosure a matter of course in science, or do the European Union's policy aims depart from or even contravene the codes of conduct in science? In order to assess how patents can improve and contribute to an already excellent science, whether it broadens our knowledge-base or skews the course of science from knowing to marketing, we have to look at the self-image of science, compare it with daily practice, and then check its compatibility with the Union's policy.

Let us begin with the ideal of science. The conception of the public life of knowledge suggests an emerging division between academic scientists and commercial scientists; the former doing research at public institutions, the latter at biotech dedicated firms. Commercial scientists are doomed to come up with knowledge that is industrially applicable, whereas for academic scientists knowledge is an end in itself. Academic scientists are driven by intellectual curiosity, rooted in the innate desire to create new knowledge; their goal is advancing

56 Park (2000), p.1173.
57 Chiarella (2008), p.1173.
58 COM (2002) 27, p.11.
59 Suizhuang (2007), p.62.
60 Ray (2005), p.199.
61 Filipkowska (2003), p.57.
62 Brockhaus (2006) vol.16.
63 COM (2002) 27, p.7.
64 COM (2007) 175, p.3.
65 COM (2002) 27, p.23.
66 WIPO (2006) 33.20.

knowledge itself.[67] Where commercial scientists pursue the private interest of profits, academic scientists are disinterested:[68] they promote the public interest in knowledge; for them the objectivity of knowledge is more important than its potential market value. And the ideal of objectivity requires publishing one's discoveries or inventions, submitting them to the critical scrutiny of a public review, mostly done by peers, and sharing one's knowledge with at least all the other scientists.[69]

The disclosure of scientific knowledge enables other scientists to replicate performed experiments or to comprehend the line of reasoning leading to an invention. And it is the successful replication, the public approval of a scientist's achievements that lend her recognition among her peers. Peer recognition 'motivates men of science to replace the value set upon secrecy with the value placed upon disclosure of the knowledge they have created.'[70] Hence, freedom of inquiry, open access to knowledge and the full disclosure of scientific results through publication are considered to be the cornerstones of academic science, which both scientists and politicians have long upheld.[71]

This has changed. Patents mean the commodification and privatization of knowledge products, and thus imply a potential restriction of the access to knowledge products. The change raised concerns among scholars. Some see science already impeded when scientific results are turned into a commodity;[72] others regard the commercialization of science as a threat to the foundations of the public scientific infrastructure.[73] To decide on potential impairments of science, we have to take into account the motives and motivations of scientists at work and see how far the ideal indeed gives guidance to science in practice, i.e. to which degree the codes of conduct overlap with the actual conduct.

The normative rule to disclose one's knowledge immediately and share it as widely as possible lets us expect a highly cooperative behaviour among scientists. And scientists indeed cooperate with each other; but at the same time they compete against each other.[74] Whether the cooperative side or the competitive side prevails differs from situation to situation and depends mainly on the chances to get recognition. The lower the chance is to get recognition, the more widespread is cooperation, and the higher the chance to get recognition, the more intense competition. Because recognition entails scientific competence and social authority, it might be identified with symbolic capital. Symbolic capital, like monetary capital, can be converted in all kinds of resources necessary to continue one's scientific knowledge production. In the competitive struggle for ever more recognition, symbolic capital is deployed by scientists in strategies of domination and monopolisation directed against other relevant knowledge producers.[75]

An ideal economic agent would hardly behave any different. The economic agent, too, would, seeking to become a monopolist, keep his knowledge secret or disclose it only incompletely. That is what scientists do – and always have done.[76] In the 17th century, well-known scientists

67 Goldman (1989), p. 76; Reichman (2003), p.335.
68 Merton (1973), p.273; Reichman (2003), p.335.
69 Merton (1973), p.273; Rai (1990), p.90.
70 Merton (1973), p.337.
71 Reichman (2003), p.317.
72 Martin (1995), p.8.
73 Merges (1996), p.146.
74 Hull (1988), p.198.
75 Bourdieu (1975), p.33.
76 Resnik (2001), p.48.

like Galileo, Newton, Hooke or Huygens codified, after they had discovered a new law of nature, its description in an anagram and published the anagram. For the time their colleagues tried to unscramble the anagram, the authors could continue working undisturbed as a knowledge monopolists. When the scientific progress approached the discovery and threatened the authors' priority, they solved the anagram and were awarded with the desired recognition. With analogous secrecy scientists treated their inventions of mechanical devices. The devices were put in a sealed box, deposited at the secretariat of the Royal Society and were to be opened only at the inventors' discretion.[77]

This secretive behaviour has not changed to date in principle. In the 20th century scientists still refuse to share ideas, data, tools, techniques or resources. Biotechnology marks here no exception. With respect of biological materials scientists are heavily reluctant to disclose their knowledge completely, before and even after the research on the materials has been published. As a rule, the more difficult and expensive the generation of the material concerned, the less likely it will be shared with other scientists.[78] Symbolic capital is operating here, not confidentiality of the few cases where personal health data of patients are at stake, or where the material has to be classified as military research. Neither withhold scientists their knowledge because they want to make sure before publication that they have developed their arguments in sufficient depth or gathered enough empirical evidence to support their conclusions in order to win the race for priority.[79] The very same race for priority leads at least equally to premature publications where scientists deliberately omit a sound verification of their results.[80]

Rather it is the desire for recognition that is half the rationale; the mutual checking of research required for approval being the other half. The secretive non-disclosure or incomplete disclosure of alleged research results shall prevent other scientists from achieving the correct results before oneself. Obviously then, it is the first half that drives scientists: if they can get recognition without mutual checking, even the critical review that decorates scientific knowledge becomes dispensable. In other words, if the only way for scientists to get recognition for their work is to make it public, then they will make it public.[81]

The first to publish is the one to get recognition. Recognition and priority are inseparably intertwined. It is the first who publishes the results of an experiment who is credited with all the recognition, not the one who replicates the experiment and therewith confirms the claimed knowledge; whereby it is the confirmation that makes scientific knowledge that robust a body, and thus must in principle be credited; however it is not. And the equally important publication of non-confirming results, by which a scientist would undermine his own reputation, cannot be enforced. But because the scientific community is urgently in need of knowledge products to create knowledge products, scientists agree that the first who makes a contribution to knowledge public goes away with all the credit. The exclusive recognition is granted as an incentive to disclose new knowledge early on so that others can use it.[82]

Thus, the established norms on how to credit recognition do in principle not differ from the policy norms of patents on how to credit exploitative monopoly rights. In the end, academic researchers and commercial researchers behave similarly with respect to their crediting

77 Hull (1988), p.323.
78 Cohen (1995), p.1715.
79 Resnik (2001), p.48.
80 Rai (1992), p.92.
81 Hull (1988), p.341 and p.350.
82 Hull (1988), p.352.

system. Both systems promote the creation and dissemination of new knowledge products by rewarding priority in exchange for disclosure.[83] Both systems deploy incentives because otherwise the participants would not disclose their knowledge to the benefit of economy and society. When scientists claim that the scientific community benefits from sharing knowledge and getting critical feedback, what outweighed by far the private interest in priority, then these scientists are in their respective field miles ahead of everyone else and enjoy preferred access to all pertinent information. Hence, they can easily share their ideas and results and receive feedback without endangering their opportunities to get full recognition.[84]

Compared to their commercial colleagues academic scientists enjoy much greater freedom to limit the disclosure of their knowledge; they may choose to withhold all but the minimum of data needed to back their published findings, or they may provide no data at all.[85] And they make use of that freedom. In fact, academic scientists fall short of the communist ideal of instantaneous and widespread disclosure.[86] And when they finally publish their results they do not give the full account, often not even enough to replicate the original experiment. Just like their commercial colleagues. This suggests that the problem of the accessibility of knowledge products does not originate with commercial interests or intellectual property rights.[87]

In sum, we expect no greater harm on science and knowledge production from patent regulations. With respect to the knowledge policy, patents only add an additional incentive to invent first. Patents decorate academic researchers, too. If anything, patent regulations are likely to be more rigorous concerning the disclosure requirements than the scientific community's autonomous norms. What might make an appreciable difference however is the timing of disclosure. Filing a patent delays publication often for months because the substance of an invention has to be checked first whether it qualifies for patentability.

83 Eisenberg (1987), p.230.
84 Hull (1988), p.352.
85 Reichman (2003), p.351.
86 Merges (1996), p.149.
87 Eisenberg (1987), p.204.

2 Legal protection of knowledge in Europe

The European patent regime is fragmented. It consists of international, supranational, and national parts. To date Member States of the European Union retain the right to grant and administer national patents. On an international level European states concluded in 1973 the European Patent Convention for granting the European patent. When granted European patents are subject to the same conditions as national patents granted by the respective Contracting State according to article 135 EPC. European patents are a bundle of national patents, and no unitary title.[88] Thus, European patents are governed after their grant by national legislation with respect to both their enforcement and validity. National authorities deciding on the validity of a European patent for their territory however must base their decision on the grounds for invalidity set out in article 138 EPC.

This would be different under the Community Patent Convention drafted in 1975 for granting the Community patent. A Community patent would be uniform in the EU and not allow for national governance. It would be governed exclusively by Regulations the EU legislated. The Community Patent Convention however has never been ratified; and the Regulations concerning Community patents from 2000 and 2009 did not go beyond a draft status either. If the Council Regulation on the Community patent should ever become law, it still supplemented national patent law of the Member States, and would not replace it.

The harmonising efforts of the European Union in patent law have been more successful with regard to biotechnology, even though the first draft of the Directive on the legal protection of biotechnological inventions from 1988 was rejected in 1995 by the European Parliament for moral reasons concerning the patentability of the human body and its parts. The second draft of the Biotech Directive contained the prohibition of patenting the human body or a part of it in its natural state. However, it was less the morally impeccable formulation of the prohibition that made the Parliament accept the Directive in 1998, but the scientific progress biotechnology meanwhile made, revealing prospective economic opportunities which mainly the United States exploited: 65% of all patents on biotechnology originated there.[89]

The enactment of the Biotech Directive caused the European Patent Organisation to amend the European Patent Convention in 2000 transposing the Directive's provisions almost literally. The amendment ensures that Member States who are Contracting States to the Convention do not get into conflict under their international obligations concerning patent law. These obligations include the ones under the TRIPS Agreement from 1994 stemming from the Member States' and the EU's membership to the WTO. The provisions of TRIPS however do not impose additional or stricter obligations on the Member States than the Directive or the Convention.

Apart from the national authorities administrating patents in Europe, two international judicial bodies influence the European patent regime: the European Court of Justice and the Boards of Appeal. The European Court of Justice shall, pursuant to article 19(1) TEU, ensure that in the interpretation and application of the Treaties the law is observed. This task includes reviewing the legality of legislative acts by EU institutions, bodies, offices or agencies according to article 263 TFEU, and interpreting these acts – like for example the Biotech Directive – in preliminary rulings according to article 267 TFEU. With respect to patents, the ECJ may have jurisdiction in disputes relating to the application of acts by the EU which create intellectual

[88] COM (2007) 165, p.5.
[89] European Commission (1996), para 1.3.

property rights, if the council confers such jurisdiction to the Court according to article 262 TFEU.

The Boards of Appeal are tribunals hosted by the EPOrg's European Patent Office which is divided into a receiving, examining, opposition, and legal section. Decisions of these sections can be appealed, pursuant to article 107 EPC, by any person who is affected by them, provided she pays the fee for appeal. The respective Boards of Appeal are responsible for the examination of these appeals according to article 21(1) EPC. To ensure uniform application of the law the Boards of Appeal shall, pursuant to article 112(1) EPC, refer any point of law to the Enlarged Board of Appeal who decides on the points according to article 22(1a) EPC.

The relationship between the European Patent Organisation and the European Union is very close with regard to the wording of patent legislation, but not mutually binding. It is very close because of the fact that all Member States of the European Union are Contracting States to the European Patent Convention. However, the European Union itself is no party to the Convention, and thus article 216 TFEU does not apply, and the European Union is not bound by the Convention.[90] In return, European Union law is not directly applicable in the jurisdiction of the European Patent Office's Boards of Appeal. Though the Boards of Appeal are recognized as tribunals, they cannot refer questions on the interpretation of Convention provisions under article 267(a) TFEU to the Court of Justice, even when European Union law has been literally transposed into the Convention.[91]

These introductory remarks on the overlapping application of the relevant legal instruments concerning the patent regime in Europe will be further outlined in the remaining chapter and will be fleshed out by case law. The outline focuses incrementally on the status of the Biotech Directive and finally opens out into a detailed analysis of the Directive with regard to patentability and protection of biological material. The analysis will reveal a considerably expanded scope of patentability and protection, whereby the scope of protection might even be wider than that of patentability. The expansion is due to low requirements for patentability, for example through lowered disclosure requirements qua deposition of biological material, and narrowly construed exceptions from patentability. Altogether, the provisions effectuate a constant blurring of the conceptual line demarcating inventions from discoveries; which in turn allows for a thorough and comprehensive exploitation of biotechnological knowledge products in the internal market.

2.1 Biotechnology in the context of the European patent regime

Patents are in the European Union largely in the jurisdiction of the Member States and thus governed by domestic law.[92] The growing importance of patents for the internal market and Europe's competitiveness on the world market however gave patents an increasingly central role in the Union's efforts of harmonisation. With the entry into force of the Lisbon Treaty finally the European Parliament and the Council are empowered by article 118 TFEU under the chapter of the approximation of laws to adopt measures which provide uniform protection of intellectual property rights throughout the Union. The new provision in the Treaty facilitates the adoption of measures in the field of patents because now unanimity of the Council is

90 C-377/98 *Netherlands v. Parliament and Council* [2001], para 52.
91 G 2/06 *Use of Embryos/WARF* (Enlarged Board of Appeal), paras 2-6.
92 C-431/05 *Merck Genéricos v. Merck & Co.* [2007], para 44.

thereto no longer required. And the Council did not even hesitate a week to make use of the new provision.

Before we come to the Council's conclusion some general remarks on patents are in order despite imminent redundancy. The remarks will help classify the conclusion within the current patent regime in Europe. Generally, patents are documents which are issued by a government officer upon application. The documents describe an invention and create a legal situation in which the patented invention can only be exploited with the consent of the owner of the patent.[93] Thus, patents consist of two parts, a descriptive one and a normative one. The descriptive part should allow any person with sufficient background knowledge, i.e. with common skills in the field, to put the invention into effect. This part then amounts to a knowledge product which is to be disclosed to the public. The normative part contains claims which both constitute and delimit the extent of protection for the invention. If the inventor of a water bucket successfully claimed protection for any container of water, he then could prevent others from producing for example bottles. Thus, it is the legal part that bestows the inventor with legal privileges in exchange for the disclosure of his invention in the descriptive part.

The owner of a patent can enforce the privilege of exclusively exploiting an invention with the aid of the state where his invention is patented. To get a patent the inventor has to file an application for his invention at the domestic patent office which publishes the application after an officer searched it for prior art, i.e. after it had been checked that similar devices are not already in use. After the publication the invention is examined to the points whether it is new, involves an inventive step, and is industrially applicable. If the invention does not fulfil these criteria or is subject to an exception from patentability, the patent will be refused; else it will be granted. A granted patent may be challenged according to article 99(1) EPC within nine months after the grant was published in the European Patent Bulletin by any person paying the opposition fee. The opposition must be filed, pursuant to article 100 EPC, on the ground that an invention is not patentable for neglected reasons, or that the invention has not been described clearly enough and thus cannot be carried out by a person skilled in the art. Is the opposition successful, then the office has to revoke the patent.[94] In Member States of the European Union the publication of the application is mandatory after eighteen months; however the lag between filing the application and the grant or refusal of a patent ranges between two to eight years with significant differences across the states.[95]

An inventor may file a European patent application at the European Patent Office in Munich for his invention in any one language of the Contracting States to the Convention. When the patent is granted however, the applicant has to translate the application into one of the official languages of all the states where protection is sought. And the translations have to be submitted within three months; else the patent is void from the beginning pursuant to article 65 EPC. Given the thirty-six Contracting States there might be up to twenty-one translations necessary. This makes the European patent a costly affair. Compared to the United States or Japan a European patent is two to three times more expensive. The costs for a European patent range on average between 30 000 € and 45 000 €; on average forty percent of these costs are expenses for translations.[96]

93 WIPO (2006) 7.1.
94 Guellec (2007), p.170.
95 Guellec (2007), p.5.
96 Guédou (2007), p.5.

Another costly aspect of the European patent is multiple litigation in case of revocation or alleged infringements of patent rights. In order to enforce his patent rights Union wide, an inventor must file infringement actions in twenty-seven states; and his competitor may do the same when she wants to obtain the revocation of his European patent.[97] Given an amount of dispute of 250 000 € the Commission has calculated that the parties have to pay up to 1 950 000 € in the first instance, and up to 1 390 000 € in the second instance in order to get binding decisions in only four Member States, namely in the United Kingdom, France, Germany, and the Netherlands.[98] Not to mention the legal uncertainty resulting from potentially conflicting decisions of the respective authorities. There are only a few companies which can bear such costs; and in particular small and medium sized enterprises face difficulties in collecting finance for their European patent applications. Hence, the European patent system entails the danger that some inventions may not be filed due to the high costs and may be kept secret instead.[99]

A central judicial organ taking decisions enforceable in all Contracting States would not only lower litigation costs of the European patent, but also ensure more legal certainty in Europe's patent regime. For these reasons a working party of EPOrg proposed the European Patent Litigation Agreement in 2004 establishing a European Patent Court with regional subdivisions which decide on the validity and on infringements of European patents. The basic idea behind the European Patent Court is that the Contracting States commit themselves to treat the decisions of the European Patent Court as if they were decisions of a national court. Thus, a decision of this European Patent Court would be enforceable in all Contracting States at the same time. In 2005 Directive 2004/48 on the enforcement of intellectual property rights was implemented in the Agreement, which then was not continued ever since.

The European Union namely strives for legal patent sovereignty, obviously reluctant to get too much involved with the European Patent Organisation. For decades the Commission has been advocating an autonomous Community patent and lastly drafted a Regulation on the Community patent on 29 September 2009.[100] The Community patent shall be subject only to the Regulation – which regulates the content, scope, limitation or exhaustion of the Community patent as well as burden of proof and licensing; but the European Patent Office shall search, examine and grant the Community patent, pursuant to article 2 Draft Regulation; what required after all the accession of the EU to the EPOrg.

Remarkably, the drafted Regulation specifies the exclusive rights of a patent holder and sets financial incentives to license a patent widely. The Community patent confers the right to prevent direct and indirect use of an invention. Whereby direct use means, pursuant to article 8 Draft Regulation, to make, import, offer, put on the market or use an invention; and indirect use means, pursuant to article 9 Draft Regulation, to supply or offer to supply parts which are essential to an invention and are intended for putting the invention into effect, except staple products. The preventing of direct and indirect use of an invention shall not boil down to an exclusive exploitation. Inventors who agree beforehand to license their patents to anybody who wants to make use of the invention shall, pursuant to article 20(1) Draft Regulation, be rewarded with reduced renewal fees for their Community patents. This article underscores the European Union's intention to gain as much knowledge as possible, and to disseminate

97 *Glaxo Group v. Genentech* [2008] EWCA Civ 23, para 29.
98 COM (2007) 165, p.8.
99 COM (2002) 2, p.21.
100 Council of the European Union. Working Document 13706/09 PI 92.

knowledge as widely as possible, in order to establish knowledge as the fifth freedom on the internal market.

On 4 December 2009 the Council concluded to introduce a Community patent – now called EU patent – together with a European and EU Patent Court which shall decide on the validity and infringements of European patents and EU patents. Such a patent litigation system would drastically reduce the patenting costs in Europe;[101] however the same saving could be achieved without duplicating patents in Europe. The European Union could work towards special provisions in the Convention for its Member States where it so deems necessary, instead of establishing the EU patent next to the European patent. Whereby such special provisions are highly unlikely: an inventor would only opt for an EU patent instead of a European patent if the EU patent is more attractive, because he would under the European patent enjoy protection for his invention in the geographically wider area of additional nine states. But why should these nine states oppose amendments of the Convention that made the European patent as attractive as the European Union wants the EU patent to be? Thus, the Council's conclusion appears to be particularistic, if not protectionist.

The European Patent Convention does not prevent the European Union from legislating in the field of patents and adopting measures that harmonise national patent law. Therewith the European Union could in practical terms form a EU patent that effectively replaced the patents of its Member States even after the accession to the Convention, as long as the harmonisation measures were compatible with the Convention's provisions. The situation would not differ much from the obligations under the TRIPS; besides that European Patents issued by the European Patent Office would become EU patents which would then be regulated by the relevant legislation of the European Union, such as Directive 98/44 on the legal protection of biotechnological inventions.

The Biotech Directive is considered to be a landmark in the development of patent law in Europe,[102] and became under rule 26(1) EPC a supplementary means of interpretation for the provisions of the Convention by the Convention's amendment in 2000. Particularly the fifty-six recitals of the Directive supply a rich stock of interpretative guidance through patentability and protection of biotechnological inventions including their ethical review.[103]

Based on the obligation of the Member States to protect biotechnological inventions under national patent law pursuant to article 1(1) Biotech Directive, article 3(1) Biotech Directive determines that inventions which are new, which involve an inventive step, and which are susceptible of industrial application shall be patentable even if they concern products consisting of or containing biological material, or processes which produce, convert or use biological material. Article 3(2) Biotech Directive determines that biological material which is by means of a technical process produced or isolated from its natural environment may be considered an invention even if the material previously occurred in nature.

Thus, as summarized in rule 26(2) EPC, biotechnological inventions are inventions which concern products consisting of or containing biological material, or processes by means of which biological material is produced, converted or used. Whereby biological material means, pursuant to article 2(1a) Biotech Directive and rule 26(3) EPC any material which contains genetic information and is capable of reproducing itself or being reproduced in a biological

[101] Danguy (2010), p.34.
[102] T 1054/96 *Transgenic Plant/Novartis* (Boards of Appeal), para 73.
[103] Jasanoff (2005), p.221.

system. Note that patenting of biotechnological inventions was possible in Europe before the adoption of the Biotech Directive. A general exclusion of inventions in the sphere of biological material could not be inferred from the Convention, either.[104] The Biotech Directive thus concretizes and specifies developments of national patent law in order to confer greater legal certainty on patents related to biotechnological inventions, but it does not introduce a new right sometimes stigmatised as 'patent on life'.[105]

The aim of the Biotech Directive is to promote research and knowledge generation in the field of genetic engineering in the European Union, and it does so by removing legal obstacles within the internal market which result from differences in national legislation and case law.[106] Different levels of protection for the same patents on the internal market would amount to a detrimental source of uncertainty for patent holders with regard to investments in research and development. The Directive thus harmonises national patent law in order to strengthen the competitiveness of the European biotech industry which should catch up with the respective industries in the United States and Japan.[107]

The potential impact of the Directive on the competitiveness of the European Union on the world market grows with the rapid spread of the application of biotechnological products and processes to other industrial branches. More and more products contain biological material or involve a process by means of which biological material is produced, converted or used, as biotechnology evolves from a gene based science to a multidisciplinary science. An ever advancing knowledge of genes and complex cell processes increasingly integrates interactions with the environment which leads on an industrial level to an incremental integration of biotechnology applications across all sectors.[108] Therefore, the significance of patents awarded within the field of biotechnology can nowadays not be underestimated.[109]

Now that the main concern of the Biotech Directive is not so much to increase the protection of biotechnological inventions, but rather to smooth existing legislative differences in that area to facilitate trade on the internal market,[110] a further concern emerges in the shape of competitiveness: the concern that many companies do not fully exploit the possibilities to make use of their intellectual achievements, which potentially impedes further developments towards a European knowledge economy. In particular academic scientists and small and medium sized enterprises lack experiences on how to best use patent rights.[111] One such possibility is a compulsory license pursuant to article 21 Draft Regulation, which might be obtained four years after a patent had been filed when the protected invention is not or only insufficiently exploited. If enacted, this provision would set remarkable limits to the discretion of a patent holder: the privilege to exploit an invention came close to an obligation to exploit it.

The legislative intentions of the European Union make it clear that it considers patents implicitly as a social contract between an inventor and society.[112] This contract must be balanced, and therefore goes beyond the recovering of the inventors' investments and the public's

[104] T 49/83 *Propagating Material/Ciba Geigy* (Boards of Appeal), para 112.
[105] C-377/98 *Netherlands v. Parliament and Council* [2001], para 25.
[106] C-377/98 *Netherlands v. Parliament and Council* [2001], para 27.
[107] Frahm (2002), p.79; Laudien (2006), p.582.
[108] OECD (2009), p.15 and 53.
[109] C-428/08 *Monsanto Technology v. Cefetra BV* [2010] Opinion Advocate General, para 1.
[110] C-428/08 *Monsanto Technology v. Cefetra BV* [2010] Opinion Advocate General, para 51.
[111] COM (2007) 165, p.11.
[112] Belt (2004), p.34; Borrás (2006), p.595.

access to knowledge incorporated in the patented invention;[113] it has the economic dimension of a knowledge economy where knowledge is commodified and traded. Given the crucial relevance of knowledge for the internal market, the European Union does not content with the lapse of the exclusive patent rights twenty years after the date of filing, as stated in article 63 EPC and reiterated in article 27 Draft Regulation; nor with the condition of sufficiently clear and complete disclosures of an invention for granting a patent, pursuant to article 83 EPC. A booming knowledge economy requires knowledge generation, knowledge commodification, knowledge protection (patents), and at last the commercial exploitation of knowledge. Thus, the European Union aims at designing a patent-integrated knowledge regime, such that patents allow the availability of knowledge products and sustain the absorptive capacity of the European companies in the internal market for these knowledge products without interfering with the growing business of knowledge trade. The very shaping of patent rights would fall short of that aim; patent law for a knowledge economy must cover the desired usage of patents, too. Incentives for licensing widely or possibilities to use dormant inventions before the expiry of the patents are means needed in addition to well established provisions of patent law like research exemptions or prior use.

Unlike the United States where the first to invent is rewarded with patent rights, Europe grants a patent for an invention to the first who files the application.[114] The European approach thus ensures legal certainty in the frequent cases of simultaneous inventions, which are the rule and not the exception, with all the consequences however entailed in the allocation of a common effort to a single person.[115] If two or more persons have made an invention independently of each other, the European patent for that invention shall, pursuant to article 60(2) EPC, belong to the person whose European patent application has the earliest date of filing – provided that the application has been published. Due to this digital all-or-nothing patent rule simultaneous inventions are hardly recognized by society, not to mention the hindrance of their societal exploitation. Other inventors are 'left out in the cold, without economic reward, without the right to make copies of their own invention, without the right to compete in the market, and without any fame.'[116]

This harsh effect is mitigated by the prior use clause. Prior use rights exist in every Member State except Cyprus. They allow an inventor to continue making use of an invention which was in use before a patent application for the invention was filed. Thus, prior use acts as a defence against a patent holder in Europe, contrary to the United States where prior use is a bar to patentability. Article 12 Draft Regulation allows in a nutshell anyone who had already used an invention in the European Union, or had seriously prepared its use before the patent was filed, to continue such use or to use the invention as envisaged in the preparations. The provision protects inventors who cannot or do not want to incur the cost for patenting, and rather invest the money in innovative efforts. However, university inventions might not fall under the prior use rights because universities usually do not use or exploit their inventions.

Universities in contrast benefit from the research exemption. The European patent regime is not intended to call into question the freedom of research in Europe. The use of patented inventions for public research for experimental purposes, as well as private research for non-commercial purposes does not constitute acts of infringement.[117] The permission to use

[113] Overwalle (2009), p.421.
[114] Guellec (2007), p.34.
[115] Boldrin (2008), p.206.
[116] Boldrin (2008), p.207.
[117] COM (2002) 545, p.20.

patented inventions for experimental research may under the so-called Bolar provision[118] be extended to commercial purposes: With the aim of facilitating the entry of generic medicines in the internal market, Directive 2004/27 on medicinal products for human use provides under article 10(6) that conducting necessary studies and trials for producing generics shall not be regarded as contrary to patent rights. Generally, experiments aimed at 'perfecting, improving or further developing protected inventions do not infringe the patent.'[119] The exemption for experimental purposes is resumed in these general terms in article 9(b) Draft Regulation. The research exemption thus bestows scientists – academic and commercial – with a privilege sui generis that shall counterbalance the privilege conferred to patent holders.

2.2 Patentability of knowledge

A patent is the first step to the privileged exploitation of an invention. Thus, patentability not only paves the way for this exploitation but also specifies what kind of knowledge products are deemed to be appropriable, and thus can be withdrawn from the public domain. The main features of patentability in Europe are common standards: European patents shall be granted, pursuant to article 52(1) EPC, for any invention in all fields of technology, provided that the invention is new, involves an inventive step, and is industrially applicable. These requirements apply to biotechnology, too, according to rule 27 EPC. And following rule 26(1) EPC biotechnological inventions are to be interpreted, supplementary, in the light of the Biotech Directive.

The reference to the Biotech Directive does not imply the consideration of concerns incorporated in domestic patent law of Member States under the implementation of the Directive. The Boards of Appeal assume the Convention to be a self-contained legal system which can be sufficiently interpreted on the Convention's provisions and object and purpose alone. Whereas the object and purpose of the Convention is not only to be sought in the legislators' intention at the time when the law was adopted, but also in their 'presumed intention' given changes of circumstances which had taken place since then.[120] Such circumstances, I would say, are considerable motives for the Contracting States to design their national patent law accordingly – where European patents finally end up after having been granted. Anyhow, the content of national patent law is said to be irrelevant to the issue of how the Convention should be interpreted, because it does not form part of the legal order established by the Convention.[121]

2.2.1 Plants, animals and varieties

The legal order of the Convention provides in rule 27(b) EPC that plants and animals are patentable. This provision, laid down in article 4(2) Biotech Directive, has been heavily opposed by the Dutch government.[122] The Netherlands demanded that in the field of biotechnology patents should be limited to biotechnological processes and not be extended to products derived from them. In other words, the Netherlands was not willing to frame living matter as a knowledge product. However, the Member State has been outvoted in the Council. Henceforth, herbal and brute chimeras are patentable and have been patented. The patent of

118 *Roche Products Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984).
119 C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 27.
120 T 19/90 *Onco-mouse/Harvard* (Technical Board of Appeal), para 4.7.
121 T 1213/05 *Breast and ovarian cancer/University of Utah* (Boards of Appeal), para 55.
122 C-377/98 *Netherlands v. Parliament and Council* [2001], para 119.

transgenic salmon granted to the Canadian company Seabright[123] caught a wide attention because a salmon eight times larger than the natural species, thanks to genetically induced growth, could supplant non-manipulated salmons from nutrition and reproduction. This however concerns the exploitation of an invention, not its patentability. For an animal or a plant to be patentable, it is required that it can only be obtained through genetic engineering and not through natural breeding.[124]

To determine the necessity of genetic engineering for obtaining a plant or an animal, a fictitious expert is needed who knows all the details related to breeding and invention: the skilled person in the art. This person embodies all the knowledge, i.e. has all the skills, needed to decide on the basis of current knowledge, i.e. given all pertinent knowledge products, the issue of what counts as natural fertilization and what as artificial invention.[125] With respect to inventions the skilled person has to identify first and foremost an inventive step. The inventive step must not be obvious and has to entail an essential progress in the field.[126] Thus, an assessment of the inventive step often requires balancing the contribution to the art, i.e. to our knowing in a field, by the patent specification from an intellectual point of view against the actual technical disclosure provided in support of what is claimed.[127] In other words, the extent of the technical achievements described in the application must be balanced against the theoretical background of the claimed invention. Such an exercise is essential in cases where the contribution to the art consists in demonstrating that something that was already theoretically conceivable based on prior art, is indeed technically feasible; and it is essential in cases, where the theoretical conception of an invention is but insufficiently backed by its technical feasibility.

Thus, in evaluating the attitude of the skilled person, one should not confuse the hope to succeed regarding the claims with the reasonable expectation of success.[128] The hope to succeed is linked to the desire that the claimed result be achieved technically; the reasonable expectation of success however is linked to the capacity to reasonably predict a successful technical realization implying an essential progress in the art, given the particular technical circumstances. The relevant question to the inventive step is, therefore, whether the skilled person, faced with the technical problem underlying an innovation, would come up with the same solution as the applicant. Then the invention is assumed to be obvious to the skilled person.[129] It is assumed to be non-obvious on the other hand, when the invention entails a step which cannot be derived from available knowledge products, called documents which equate mainly to published journal articles.[130]

Such an evaluation requires of course the disclosure of the applied techniques. The disclosure is the sine qua non for any assessment by the skilled person, as provided for in rule 83 EPC. If the descriptive part of an application does not explicitly disclose non-obvious techniques, the applicant may not hope to succeed with her patent application even though the involved techniques are actually feasible. Hence, the patent for transgenic cattle of any desired phenotype as a result of in vitro maturation of bovine egg cells was not allowable already at an early stage of the examination process, because the genetic engineering of the in vitro maturation

123 EP 578 653.
124 COM (2002) 545, p.13.
125 Dewey (1925), p.656.
126 WIPO (2006) 1.24 and 7.29.
127 T 743/98 *Targeting proteins/Pharming* (Boards of Appeal), para 4.
128 T 666/05 *Mutation/University of Utah* (Boards of Appeal), para 59.
129 T 743/98 *Targeting proteins/Pharming* (Boards of Appeal), paras 9 and 17.
130 T 669/97 *Chimeric antibodies/Celltech Therapeutics* (Boards of Appeal), para 18.

technique had not been explicitly disclosed.[131] The skilled person has to examine the disclosed subject-matter of an invention, whereas the skills required for the examination are twofold: the examining person has to command the skill which enables her to decide whether the invention can successfully be carried out, and the person has to command the skill which enables her to decide whether the predicted success involves an inventive step.

It is pleonastic to remark that the skills are limited by what the person knows; or is allowed to know because the skilled person is a legal fiction. But: Where to set the limits in the unlimited progress of science? When to freeze the public life of knowledge? Within the dynamics of scientific development and the sheer number of knowledge products produced, constituting this development, it can be, to start with, impossible to determine how many of them, and in particular which of them, the person should have consulted to train her skills. In other words, the non-obviousness of an inventive step depends very much on the skills afforded to the fictitious examining person;[132] and for the determination of the skills there exists no guidance outside the public life of science, of which both the applicant and the examiner form an integral part. Whether an alleged invention contributes to the art finally hinges on its public approval, and not on a formal certificate like the patent document. Thus, it is often only with the benefit of hindsight that one is tempted to know what the skilled person would have had to do at the time of examination in order to arrive at the claimed subject-matter.[133]

In any case, as things stand now, the circumstances and changes of circumstances, in whose light the Convention is to be interpreted, are the state of the art in technology and science. It is scientific discoveries and technological developments, not political concerns that may initiate a shift in the Convention's interpretation. The technocratic policy of the Boards of Appeal aims at shielding the international organisation from political influences, preserving for itself a neutral position when restricting issues of patents and patentability to technical feasibility and novelty. The political aspects of patent law – beyond the framing of knowledge – are left to the Contracting states. These political aspects are usually related to the exploitation of a patented invention and thus fall in the post-grant phase of a patent which lies, with the exception of opposition procedures, outside the jurisdiction of EPOrg. The Contracting States may regulate this phase quite comprehensively given that the European Patent Office allows for wide patentability. Because article 52(1) EPC provides for a general rule of patentability in all fields of technology, including biotechnology, any exception to patentability has to be construed narrowly.[134]

Such exceptions are, pursuant to article 4(1a) Biotech Directive, plant and animal varieties. Plant and animal varieties are, as confirmed in article 53(b) EPC, not patentable. The non-patentability of plant varieties does not mean that they are excluded from appropriation; rather they enjoy their own legal protection under Regulation 2100/94 on Community plant variety rights. Plant variety rights are, pursuant to article 1 Plant Variety Regulation, an exclusive form of industrial property rights for plant varieties akin to patents. These rights require for the production and reproduction, the conditioning for the purpose of propagation, and the selling, marketing, or stocking of plant varieties the authorization of the right holder, pursuant to article 13(2) Plant Variety Regulation, whereas it is provided for experimental exemption in article 15 Plant Variety Regulation, and farmers are allowed to use their harvest for propagating purposes on their own acres, pursuant to article 14(1) Plant Variety Regulation.

131 T 608/00 *Transgenic bovine/Pharming* (Boards of Appeal), paras 2 and 8.
132 Doll (1998), p.690.
133 T 666/05 *Mutation/University of Utah* (Boards of Appeal), para 63.
134 T 320/87 *Hybrid plants/Lubrizol* (Boards of Appeal), para 6; T 19/90 *Onco-mouse/Harvard* (Technical Board of Appeal), para 4.5.

The main difference to patents is the duration of the protection and the conditions for granting a plant variety right.

Plant variety rights are upheld up to thirty years according to article 19(1) Plant Variety Regulation. And a plant variety may be protected according to article 6 Plant Variety Regulation, if it is distinct, uniform, stable, and new.[135] The distinctness hinges on characteristics that result from a particular genotype or a combination of genotypes, whereas only one different characteristic between two varieties – for example the beginning time of flowering – is not sufficient to establish distinctness.[136] If the genes effect a different growth within one plant variety, this alone is deemed to be a lack of uniformity.[137] Hence, some plant varieties are neither in the scope of plant variety rights nor are they patentable.

The way the Biotech Directive presented in recital 30 the Plant Variety Regulation's definition of a plant variety caused an avoidable confusion in European patent law. It says that a variety was defined by its whole genome and therefore possessed individuality and was clearly distinguishable from other varieties. Apart from the distinctiveness one hardly recognizes plant varieties as defined in article 5(2) Plant Variety Regulation where plant varieties are plant groupings within a single botanical taxon of the lowest known rank, whereby a grouping can be defined by characteristics resulting from a given genotype or a combination of genotypes, and can be distinguished from other plant groupings by said characteristics, and can be propagated unchanged, i.e. the groupings remain uniform and stable. Thus, the reference to genotypes serves merely to trace a plant grouping's characteristics back to genes. Therewith other factors that have an impact on the characteristics of a plant grouping, such as climate, soil or fertilisers are excluded when determining a plant variety. The genome specifies a plant variety as well as failed plant varieties which do not express uniform characteristics over time.

Therefore, the Enlarged Board of Appeal ruled with some justification that plants grown from cells, into which a gene sequence conferring resistance to herbicides had been inserted, amounted to a plant variety within the meaning of article 53(b) EPC.[138] The plants uniformly displayed the lasting characteristics of a specific resistance which distinguished them from other plants of the same species. Consequently, these genetically modified plants could be regarded as not patentable. Then the Board went on and ruled that generally *any* genetically modified plants were non-patentable plant varieties. This ruling however not only made the conditions under article 6 Plant Variety Regulation futile but also undermined one of the principal objectives of the subsequent Biotech Directive.

Before coming to this objective, recital 32 of the Biotech Directive points out that genetic modification of plant varieties is excluded from patentability, if the invention concerned consists only in that genetic modification. In other words, a plant variety cannot be patented if the plants are solely raised in vitro instead of in vivo. Whether a plant variety is the result of traditional breeding techniques or the result of genetic engineering does not touch the conditions of distinctness, uniformity and stability for new plant groupings. The mere fact of obtaining plants by means of genetic modification does not privilege the producers of such plant varieties relative to breeders of plant varieties resulting from traditional breeding only.[139]

---

135 A 2/98 *Swedish University of Agricultural Sciences* (Board of Appeal), para 1.
136 A 5/2007 *Schräder v. Hansson* (Board of Appeal), para I.
137 A 11/2008 *Rústicas del Guadalquivir v. Community Plant Variety Office* (Board of Appeal), para 6.
138 G 3/95 *Plant cells/Plant Genetic Systems* (Enlarged Board of Appeal), para 5.
139 G 1/98 *Transgenic plants/Novartis II* (Enlarged Board of Appeal), para 5.3.

These remarks on genetic engineering of plants prepare a principle objective of the Biotech Directive: the exception to the exception of patentability. Pursuant to article 4(2) Biotech Directive, plant and animal varieties shall be patentable, 'if the technical feasibility of the invention is not confined to a particular plant or animal variety.' Confusingly, the Directive goes on to specify in recital 31 that a plant grouping characterised by a single gene – instead of being characterised by its whole genome – is not covered by plant variety rights, and is therefore patentable. To know a gene responsible for the expression of a plant variety's characteristics would arguably surrender the variety to the patent office. This however cannot be meant.

The supporting recital 29 of the Biotech Directive does not unambiguously clarify the context. It declares that plants are patentable, if the application of the invention is not technically confined to a single plant variety. This led the European Court of Justice to rule that inventions which incorporate only one gene and concern a grouping wider than a single plant variety may be patented. From which followed that a genetic modification of a specific plant variety is not patentable, but a modification of wider scope, concerning, for example, a species, may be.[140] The Court's conclusion however runs counter to the wide definition of varieties given in article 5(1) Plant Variety Regulation which comprises varieties of all botanical genera and species. Thus, a modified species may as well be protected by plant variety rights. The confusion stems from the interpretative emphasis on the grouping rather than on the invention. A claim encompassing plant groupings which embrace more than one variety is not the decisive element in the issue of a plant's patentability. It is rather the result of a biotechnological invention – applied to plants. As a result of this application, patents may be granted for genetic modifications of plants, as they go beyond the traditional techniques of breeders who experiment at the level of individual varieties only.[141]

A genetic modification of plants that goes beyond traditional breeding techniques is the insertion of a prepared gene. In this case the invention is the gene, not the plant; for example a gene that results in a plant's resistance to herbicides or a specific herbicide. Such a gene expression may be new, involve an inventive step, and be agriculturally applicable. This distinguishes the gene from natural genes. The colour of florescence, the shape and size of leaves or fruits do not amount to an invention, though resulting from a gene transfer. This gene transfer results in the combination of existing alleles, achievable by way of traditional breeding; whereas the resistance to herbicides introduces a new allele to the genome of a particular plant. Outside of a plant the prepared gene would be nugatory, that is why it has to be applied to a plant which again requires some technical efforts. But in principle, the resistance to herbicides is applicable to all plants up to the taxonomic rank of a class. The invented gene may be inserted in potatoes or apples, or in Selma or Adretta, or in Elstar or Braeburn respectively. Strictly, it is the invention incorporated in a plant that is patentable as a plant because the invention cannot be without the plant. In sum, whenever a concept of genetic engineering is the invention, which invention is applicable to more than one variety, the resulting products from the genetic modification shall be patentable, even if they are plant varieties.[142]

[140] C-377/98 *Netherlands v. Parliament and Council* [2001], para 45.
[141] Guellec (2007), p.122.
[142] T 1054/96 *Transgenic plant/Novartis* (Boards of Appeal), para 96.

2.2.2 Essentially biological processes

Another exemption from patentability are, pursuant to article 4(1b) Biotech Directive, essentially biological processes for obtaining plants and animals. In this regard recital 33 Biotech Directive demands to define when a process for the breeding of plants and animals is essentially biological without giving any further hint. Consequently, an essentially non-biological process for the production of plants and animals is patentable; the difference however between essentially biological and essentially non-biological processes is in the absence of the demanded definition to date to be assessed by the courts.[143] The Boards of Appeal may consult rule 26(5) EPC which specifies that processes for the breeding of plants and animals shall be regarded as essentially biological, if it consists entirely of natural phenomena such as crossing and selection.

This additional provision however puzzles the judicial bodies of the EPOrg more than it clarifies the situation. The puzzlement roots in the circumstance that crossing and selection usually are no natural phenomena but elements of systematic breeding. These processes would not occur without human intervention.[144] Human intervention alone, on the other side, is not deemed to be a sufficient criterion for being essentially non-biological. The intervention of man might only mean that the process was not a purely biological process.[145] The technical substitution of one step in a biological succession of steps may leave the whole process essentially biological insofar as the substitute is trivial. Remarkably, the use of molecular markers which segregate a desired trait of a plant is reckoned among well-known breeding techniques that do not go beyond the trivial.[146]

This assessment is remarkable because the wording of rule 26(5) EPC seems to require a very narrow interpretation of essentially biological processes. The element of entirely natural phenomena should already be infringed by any non-biological feature of a technique applied by man and thus no longer allow for an essentially biological process. However, the emphasis of article 4(1b) Biotech Directive lies rather on the process for producing animals and plants, and lesser on the biological characteristic of this process. That is evident from the context of the provision which is about plant and animal varieties. Thus, not only shall varieties be exempted from patentability but also 'natural' processes necessary for breeding varieties. To become an essentially non-biological process, therefore, the established processes for the production of plants and animals need to be altered appreciably.

The appreciable alteration of traditional breeding techniques might consist in a non-trivial feature of the breeding process or in a non-trivial realignment of the succession of the known process steps. In other words, it must go beyond crossing and selection, i.e. mating varieties and selectively propagating descendants with desired traits. Thus, technical interventions in a plant's reproduction cycle such as weighing and drying of seeds do not take the technique outside the realm of traditional breeding;[147] nor does transporting plants from remote geographical locations for crossing purposes with domestic varieties, because plants would not naturally hybridize even if they were located in the same habitat – hybridization requires in any case the intervention of a breeder.[148] To be patentable, article 4(1b) Biotech Directive requires for a breeding process to be essentially non-biological some kind of human interven-

[143] COM (2002) 545, p.15.
[144] T 83/05 *Broccoli/Plant Bioscience* (Boards of Appeal), para 53.
[145] T 320/87 *Hybrid plants/Lubrizol* (Boards of Appeal), para 6.
[146] T 83/05 *Broccoli/Plant Bioscience* (Boards of Appeal), para 66.
[147] T 1242/06 *Tomatoes/State of Israel* (Boards of Appeal), para 8.
[148] T 83/05 *Broccoli/Plant Bioscience* (Boards of Appeal), para 66.

tion; what kind of human intervention is finally left to be decided by the person skilled in the art of breeding.

What shall be patentable, even if essentially biological, are microbiological processes according to article 4(3) Biotech Directive and rule 27(c) EPC respectively. The patentability entails products obtained by microbiological processes as long as the products are no plant or animal varieties. The provision is consistently mirroring article 4(2) Biotech Directive on plant varieties to the process of obtaining them: As varieties are patentable if microbiological inventions are implanted in a variety, so are processes of obtaining them if they represent a microbiological invention. Thus, the patentability of microbiological processes repeats the importance attributed to technological inventions in genetic engineering. If these inventions deploy their industrial applicability only in plant varieties or in essentially biological processes for obtaining them, then the provided exception from patentability for both shall no longer apply.

2.2.3 Human body and its parts

Patentability with respect to the human body and its parts follows a similar legal construction. The construction opens with the exception. Pursuant to article 5(1) Biotech Directive, the human body is exempted from patentability; whereas the human body is meant to include all the various stages of its formation and development. This provision is literally transposed into rule 29(1) EPC. It evidently forbids the patenting of totipotent stem cells, since each of these cells can develop into a human body on its own. The legal situation is less clear with regard to pluripotent stem cells, which are not so capable. Pluripotent stem cells develop only into a limited range of specialized cell types. They are used for therapeutic purposes to reproduce united cell structures with the genetic information of a patient, such as tissues, to treat a patient's disease without the risk of being rejected by the patient's immune system.

Pluripotent stem cells represent an early phase in the incremental specialization during the formation of a living being, and thus could just as well be regarded as a stage of a human's development. Because of the rapid progress in stem cell research and apparent divergences between Member States as regards the acceptability of research relating to embryonic stem cells, the Commission considers that it is premature to further define the developmental stages of a human body to be excluded from patentability.[149] Harmonisation only becomes feasible when scientific progress clarifies the risks and benefits of modifying stem cells on a technical level, such that the Member States can agree on a common policy. Until then they are free to design their own national patent law, and to revoke European patents for their territory when necessary.

Equally exempted from patentability under article 5(1) Biotech Directive are parts or elements of the human body, including gene sequences that are simply discovered. This provision expresses the general patent rule that only inventions and not discoveries or scientific theories can be patented, as stipulated in article 52(2) EPC. The interesting issue here is where to draw the line between an invention and a discovery. The tension between both becomes obvious in the exception to the exception: the patentability of elements belonging to the human body.

Article 5(2) Biotech Directive provides that elements of the human body, including gene sequences, may constitute a patentable invention if they are isolated or otherwise produced by

[149] COM (2005) 312, p.5.

means of a technical process, even if the structure of the elements is identical to that of natural elements. This provision is literally transposed into rule 29(2) EPC which specifies rule 27(a) EPC stating that biological material isolated from its natural environment can be patented even if it previously occurred in nature. However, it is hardly conceivable, especially in biology, how a researcher could discover anything about living matter without isolating it from its natural environment. Only few scientists work as field researchers, most of them detect their discoveries in the artificial setting of a laboratory. In this sense, geneticists are privileged relative to researchers from other faculties who cannot patent the elementary particles or inorganic molecules they isolate from atoms or alloys.

The only hurdle a geneticist has to take in order to get a patent for isolated elements like a sequence of the human genome, are the conditions of patentability that apply in all other areas of technology – provided that the patent does not extend to the human body. To comply with the condition of industrial applicability it is necessary, in case of gene sequences, to specify which protein it codes for or what function it performs according to recital 24 Biotech Directive. Furthermore, recital 21 Biotech Directive requires that the sequence results from techniques which human beings alone are capable of putting into practice and which nature itself is incapable of accomplishing. In other words, the preparation of the sequence requires an inventive step in the process of identifying, purifying or classifying a gene. Thus a sequence of the human genome is patentable, when it is the result of inventive, scientific or technical efforts; and it extends to its natural state in the human body only where necessary for the achievement and exploitation of a particular industrial application.[150]

The industrial application of the sequence is closely related to the sequence's function – which must be specified. This should not conceal the fact that both sequences and inventions based on sequences are patentable on their own – and have indeed been patented. A notorious example is the BRCA1 gene, a gene that codes for a protein capable of suppressing breast cancer. Certain mutations in the BRCA1 gene thus increase the risk for breast cancer. In 2001 the US-American company Myriad Genetics got the European patent granted for BRCA1,[151] which was revoked in 2004 because the sequence has been wrongly represented in the patent description by Myriad. The company then conveyed its claims to the University of Utah which finally got two European patents concerning BRCA1 in 2008: one on the gene sequence,[152] and one on the application of the sequence.[153]

The European Patent Office granted the patent for the BRCA1 gene sequence based on the isolation requirement of rule 27(a) EPC. In isolating the gene, a chemical substance characterized as nucleic acid had been obtained by a technical process, whereby the substance comprised gene sequences of the human BRCA1.[154] In order to apply BRCA1 for diagnosing risk patients of breast cancer, mutations had to be identified on the gene that prevented the production of the tumour suppressing BRCA1 protein. Because these mutations had not been obvious, finding a mutation that allows for the development of effective screening for inherited breast cancer amounted to an inventive step.[155] This line of argument reveals the smooth passage from a discovery to an invention, from non-patentability to patentability. First the gene BRCA1 was discovered together with the protein it codes for and the latter's role in the cycle of cell reproduction, then mutations were discovered, and finally a correlation between a

[150] C-377/98 *Netherlands v. Parliament and Council* [2001], para 75.
[151] EP 699 754.
[152] EP 705 903.
[153] EP 705 902.
[154] T 1213/05 *Breast and ovarian cancer/ University of Utah* (Boards of Appeal), para 45.
[155] T 666/05 *Mutation/University of Utah* (Boards of Appeal), para 61.

mutation and a disease was discovered. The only 'invention' involved in the claim for the diagnostic application is the technical process of cloning the BRCA1 gene. But once again, the successful isolation of the gene prepares the ground for it being patentable, because in order to get the knowledge required to carry out the diagnosis, it was necessary to isolate the relevant gene from the human body.[156]

It seems to be the will of the EU legislator that the isolation of a human gene sequence amounts to an invention, and therewith to a patentable knowledge product, provided that a) the isolation results from a technical process used to identify, purify and classify genes, and b) the protein codified by the isolated gene sequence is specified. For such inventions inventors do not have to put much into practice. Modern sequencing machines decode gene sequences within hours and determine which protein a sequence codes for by comparing the results with sequences of a database. Thus, one could with a minimum input of innovation or creativity gain a maximum of rights in form of a gene patent.[157] The only, virtual, gatekeeper against gene patents with highly speculative applications based on potential functions of a sequence is the person skilled in the art, who, in principle, may require from case to case a varying description as to the applicability or the specific function of the sequences concerned, depending on the knowledge available; and thus this person may shift this requirement as the use of genes for diagnostic and therapeutic purposes spreads.[158]

The main concern with respect to the patentability of human gene sequences in Europe appears to be the concern that patented sequences do not extend to the human body. To oppose the fear of alienated human bodies or parts of it, isolated gene sequences are deemed to be different from gene sequences inherent in a human body. While it is uncontroversial that a gene patent does not amount to an appropriation of parts of the human body concerned, because a patent confers the privilege of protected exploitation, not rights of ownership,[159] it remains controversial whether the argument holds that a gene patent does not cover the gene as it occurs in the human body, since genes in the body were not in isolated and purified form which is the subject of the patent.[160] Others consider the argument to be a lawyer's trick that circumvents the prohibition on the direct patenting of genes in the human body but which, in practice, reaches the same result.[161]

The controversy on the patenting of human gene sequences entered a new stage with the judicially ordered revocation of Myriad's patents on BRCA1 in the United States in 2010. The ordered revocation comprises seven patents granted in 1998 to the biotechnology dedicated firm with claims on an isolated DNA molecule possessing a nucleotide sequence that translates into the BRCA1 protein, and on a diagnostic process of identifying certain mutations in the BRCA1 gene of patients. The ordering judge rejected the claims' referral to inventions and classified the gene sequence and diagnostic method as referring to laws of nature. Thus, the alleged inventions are considered to be discoveries. The crucial move in the judgement consists in regarding DNA essentially as the physical embodiment of information, and not as a chemical substance that can be obtained by technical processes.[162] If now information is the

[156] T 80/05 *Method of diagnosis/University of Utah* (Boards of Appeal), para 58.
[157] Belt (2004), p.36.
[158] COM (2002) 545, p.17.
[159] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 199.
[160] Doll (1998), p.689.
[161] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 3.
[162] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 125.

unique characteristic of genes, then there is no longer a difference between genes in the human body and isolated genes because the information inside the human body coincides with the information outside of it: the information is universal. The universal aspect of information makes the connection to laws of nature: genes embody laws of nature, those laws that codify universally for the same proteins – though not necessarily those that define the construction of the human body[163] because that would imply a conception of genetic laws that ignores the decisive role played by epigenetic factors.

The judge dismissed the industrial applications of the isolated BRCA1 gene on the basis that the applications derive their utility from the circumstance that the isolated DNA possesses the same nucleotide sequence as the target DNA of risk patients.[164] Thus, the unique characteristic of the sequence, derived from a product in nature, does not possess a new or distinctive form, quality or property as required under U.S. case law. In Europe however a structural identity of isolated and wild-type gene sequences is allowed for under article 5(2) Biotech Directive and rule 27(a) EPC. European patent law rather addresses the conditions of novelty, inventive step and industrial applicability; and exceptions like discoveries or scientific theories are narrowly interpreted. A formerly not isolated sequence – though occurring in nature – is considered to be new and patentable as long as it is not simply discovered according to article 5(1) Biotech Directive and rule 29(1) EPC. The U.S. court contends that the identification of BRCA1 gene sequences is no simple discovery but unquestionably a valuable scientific achievement for which Myriad deserves recognition; recognition but not patent privileges.[165]

Genes understood as carriers of universal information, written, read, transcribed and translated according to laws of nature may be excluded from patentability because even a highly difficult process of deciphering sequences in the end merely reveals the universal code determined by nature: it is a sophisticated discovery but still a discovery. However, even if one follows this interpretation of genes, it remains questionable whether the characteristic of discovery extends to their utility in industrial applications. A hard disk is not being prevented from patentability because it heavily makes use of the discovered giant magnetoresistance in nature. Similarly, an isolated gene sequence might be used in applications, for which the wild-type sequence is unsuitable,[166] such as molecular diagnostic tests, the biotechnological production of pure BRCA1 protein, or medical treatments based on gene therapy. The U.S. court dismissed the argument of diagnostics together with the pertinent patent right with the counterargument that the diagnostics boils down to comparing two gene sequences which is no more than gathering information.[167]

If a gene is conceived as information, then the gene remains information in all kinds of applications. Because the information is inscribed in genes by nature, it cannot be invented by men but only be discovered. If a gene is conceived as an active chemical substance, then the gene can in principle be applied industrially to varied purposes. Because these purposes might not be found in nature, new information is generated and our knowledge broadened such that

[163] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 124.
[164] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 130.
[165] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 135.
[166] T 558/03 *Wild-type p53 gene/Johns Hopkins University* (Boards of Appeal), para 4.
[167] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 146.

the gene amounts to an invention rather than to a discovery. The fine line between discovery and invention blurs because both build on knowledge and contribute to knowledge; both require acknowledged skills. Thus, it is not so much the distinction between immaterial information and material substance that matters, but the political will to commodify genes and make expertise in genetics an asset on the market. The European patent regime clearly epitomizes this will – as long as the patent does not impair the integrity of the human body.

2.2.4 Diagnostics and therapies

The integrity of the human body is central in diagnostics and therapies of illnesses, too. Because medical and veterinary practitioners shall be free to take the measures they consider suited to treat diseases by means of investigative methods,[168] processes for treatments of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body are not patentable, as recital 35 Biotech Directive states; with the exception of products, particularly substances or compositions of substances, for use in any of these methods, as article 53(c) EPC further specifies.

Therapies, exempted from patentability, comprise any curing and prophylactic treatment of diseases. Therapies do not comprise however any device deployed for therapeutic purposes. Such devices are not patentable if and only if they control the therapy. If there exists no functional link between the inventive part of a therapy device and its therapeutic effect, then the device cannot be excluded from patentability. Thus, as long as the practising physician determines for example when and how much of which drug a device feeds to the human or animal body, the device may be patented.[169]

Diagnostic methods are harder to assess. The legal texts neither contain particular steps pertaining to diagnostic methods nor non-committal remarks on diagnosis or diagnostic purposes in general. It just says 'diagnostic methods', what caused the Enlarged Board of Appeal to determine the concept of a diagnostic method. A diagnostic method consists accordingly of several steps, all of which must be given in order to exclude the method from patentability.[170] The steps of a diagnostic method, identified by the Enlarged Board, can be distinguished in theoretical and technical steps. The theoretical steps establish the diagnosis and what led to it. And the technical steps cover the instruments and apparatuses deployed in the diagnosis. Thus, theoretically a disease or malformation is identified based on physiological or genetic connections with the clinical picture, which in turn are based on data gained from technical examinations of the human or animal body.[171]

In short, examination, comparison, anomaly detection, and conclusion account for diagnostic methods. All these features must be related, implicitly or explicitly, to methods which shall not be patentable. Any additional technical feature may be ignored when assessing the diagnostic character of a method even if practised on the human or animal body. Such features may not constitute an exclusion from patentability;[172] whereby an application to the body must necessarily be included in the technical step. Method steps performed on fluids or tissue samples of a body remain patentable insofar as the fluids or tissue are not returned to

[168] G 1/04 *Diagnostic methods* (Opinion Enlarged Board of Appeal), para 4.
[169] T 245/87 *Controlled drug administration implant/Siemens* (Boards of Appeal), paras 3.2.3 and 5.1.
[170] G 1/04 *Diagnostic methods* (Opinion Enlarged Board of Appeal), para 6.1.
[171] G 1/04 *Diagnostic methods* (Opinion Enlarged Board of Appeal), para 6.2.4.
[172] T 1197/02 *Detection of glaucoma/Australian National University* (Boards of Appeal), para 2.2.

the same body.[173] Thus, the diagnostic testing of blood is patentable, whereas dialysis is not. The application of a technical method step requires no specific type or intensity, i.e. it need not be applied directly to the human or animal body. The practise on a body is thus interpreted broadly and implies any interaction with the human or animal body, necessitating the presence of the latter.[174] And a technical method not practised on the human or animal body, but requiring a surgical intervention is finally not patentable either.[175]

2.2.5 General exemption of immoral inventions

A diagnostic test not practised on the human or animal body, a genetically engineered plant trait, an isolated gene, an essentially microbiological process or any other biotechnological invention that got over the provided for hurdles of exemptions might still be not patentable, if its commercial exploitation offends public order or morality. Pursuant to article 6(1) Biotech Directive and article 53(a) EPC the commercial exploitation of an invention is not deemed to be offensive just because it is prohibited by law or regulation. The restriction builds on the assumption that exploitations need not be prohibited on moral grounds only, but can be based on a lack of knowledge as well – for example concerning the risks for health or environment emanating from biotechnological products. Such concerns led to the moratorium of genetically modified organisms in Europe from 1998 to 2004. An inventor anticipating a change in legal situation that would allow the exploitation of the invention shall therefore be entitled to get a patent for the invention.

Inventors shall not be chiselled out of the potential benefits invested in their inventions. Where the legal prohibition of exploiting an invention is not sufficient to refuse patenting, the legal permission of patenting is regularly taken to be sufficient not to refuse patenting on moral grounds. An invention expressly admitted under the Convention thus cannot in principle offend public morality.[176] Sometimes already the mere existence of law or regulation is a sufficient indicator for an invention not offending public morality. Moral concerns, even though controversial among Member States, may not rule out the necessity of promoting biotechnological inventions with patents in Europe as established by the Biotech Directive.[177] Hence, moral exemptions from patentability apply only in limited occasions.

A guide to these limited occasions is provided by article 6(2) Biotech Directive and rule 28 EPC respectively. The therein listed processes, such as the cloning of human beings or the modification of their germ line genetic identity, are exempted from being patentable in particular. And this means – in particular – that the list is not exhaustive but gives instead, pursuant to recital 38 Biotech Directive, a general guidance to interpreting the reference to public morality. Consequently, inventions which do not fall within the provided list thereby do not escape article 6(1) Biotech Directive and article 53(a) EPC which require for immoral inventions a general exclusion from patentability.[178] Rather, the list epitomizes, as indicated in recital 40 Biotech Directive, an assumed consensus on public morality among Member States. Such a consensus is founded on the totality of the accepted norms which are deeply rooted in

[173] T 666/05 *Mutation/University of Utah* (Boards of Appeal), para 79.
[174] G 1/04 *Diagnostic methods* (Opinion Enlarged Board of Appeal), para 6.4.4.
[175] T 1005/98 *Manufacture of endoprosthesis/Schuster* (Boards of Appeal), para 2.3.
[176] T 272/95 *Howard Florey Institute of experimental Physiology v. Die Grünen* (Boards of Appeal), para 8.
[177] G 1/98 *Transgenic plants/Novartis II* (Enlarged Board of Appeal), para 3.9.
[178] T 272/95 *Howard Florey Institute of experimental Physiology v. Die Grünen* (Boards of Appeal), para 7; T 315/03 *Transgenic Animals/Harvard* (Boards of Appeal), para 6.1.

European society and civilisation.[179] References to morality must therefore be based on an accepted standard in European culture.[180]

The reference is smooth and can be considered uncontroversial when it refers to express provisions like the non-patentability of uses of human embryos for industrial or commercial purposes in article 6(2c) Biotech Directive. Here, the controversy is centred around the elements of human embryos or commercial purposes, but not on its moral abjection. Though it is generally acknowledged that the wording of commercial purposes means the distinction to diagnostic and therapeutic purposes stated in recital 42 Biotech Directive, so as to ensure that inventions for diagnostic or therapeutic purposes, applied to the human embryo and useful to it, may be patented,[181] many important elements remain undefined. Most importantly, the term of a human embryo itself. Neither the EU nor the EPOrg have tried to define the term, presumably well aware of the different definitions employed in national laws regulating embryos.[182] Such a definition however becomes ever more pressing.[183] Given the lack of a unified use of the term within Europe and the resulting slight chance that any pertinent ruling will find wider acceptance, it is quite likely that the ECJ will remand the question for a definition of 'human embryo' and leave it to the domestic courts to decide on the matter following national law until the European legislators undertake further harmonising steps.

The last item on the list of immoral inventions concerns modifications of the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, according to article 6(2d) Biotech Directive. It gained some publicity with the patenting of the onco-mouse. The genetic identity of the onco-mouse has been modified such that it is very susceptible to cancer, and thus in the eyes of many scientists suitable for cancer research. Initially in 1992, the patent covered all genetically modified mammals but humans, was then narrowed down in an opposition procedure to rodents in 2001, and finally to mice only in 2004. In the first decision the public morality check consisted mainly in weighing the suffering of animals on the one hand, and the invention's usefulness to mankind on the other hand.[184] This balancing test has been refined in the sense that already a likelihood of suffering to animals requires the counterweight of medical benefits to man or animal. And most importantly, the patent should only cover animals whose suffering is balanced by a medical benefit.[185]

Animals are thus patentable even though they may suffer from their genetically induced diseases when three matters are established concomitantly: likely animal suffering, likely substantial medical benefit, and the necessary correspondence between the suffering and the benefit in terms of the animals concerned.[186] And it is this correspondence Harvard University failed to meet in its patent application; it could not establish that rodents, not to mention mammals, in general are suitable for beneficial cancer research, whereas mice were at least reported to be useful for imaging and preclinical screening of breast cancer. A patent that covered the likely suffering of rodents was therefore considered immoral; the likely suffering of mice in contrast to be moral – and the patent was granted for the genus, not for the order.[187]

[179] T 356/93 *Plant cells/Plant Genetic Systems* (Boards of Appeal), para 6.
[180] T 315/03 *Transgenic animals/Harvard* (Boards of Appeal), para 10.10.
[181] T 1374/04 *Primate embryonic stem cells/WARF* (Boards of Appeal), para x.
[182] G 2/06 *Use of embryos/WARF* (Enlarged Board of Appeal), para 20.
[183] C-34/10 *Brüstle v. Greenpeace* [pending].
[184] T 19/90 *Onco-mouse/Harvard* (Technical Board of Appeal), para 5.
[185] T 315/03 *Transgenic animals/Harvard* (Boards of Appeal), para 9.1.
[186] T 315/03 *Transgenic animals/Harvard* (Boards of Appeal), para 9.7.
[187] T 315/03 *Transgenic animals/Harvard* (Boards of Appeal), paras 12.2.3 and 13.2.4.

Animal experiments in particular, and genetic engineering in general are not free from moral resistance in Europe – against the legal assumption. Based on article 6 Biotech Directive and rule 28 EPC the courts may rely on a legally expressed consensus that in the current European culture animals are on the one hand respected as sentient beings, but on the other hand the very same animals are regarded as suitable for the testing of drugs and curative methods before their administration to humans.[188] This consensus may change. Also with respect to the environment; how people want their environment to be. There is thus no warrant that plant biotechnology could be regarded as offending public morality no more than traditional selective breeding.[189] That time might come. And though laws and morality support each other, morality remains supplementary to law and is thus interpreted narrowly not to override legal provisions. In other words, the influence of moral arguments on legal decisions is tacit or little.

The influence is the lesser the wider the range of the law: on a European level compared to the national level fewer arguments can be build on public morality due to growing difficulties of reaching a consensus. Moral arguments have subsidiary characteristics and thus are better hosted in Member States. According to the ECJ it is for each Member State to determine in accordance with its own scale of values what counts as public morality on its territory.[190] Public morality amounts to the scope for manoeuvre necessary to consider the specific difficulties to which the exploitation of inventions may give rise in the social and cultural context of each Member State, a context which the national legislative, administrative, and judicial authorities are better placed to understand than are the authorities of the European Union.[191] This is acknowledged in recital 39 Biotech Directive where it says that public order or morality correspond in particular, i.e. not exclusively, to moral principles recognised in a Member State – not all Member States. A Member State providing a relative standard for morality entails that a European patent which passed rule 28 EPC still may be revoked on moral grounds in one Member State, but not in another.

It should be remembered however that morality can only be invoked against the exploitation of an invention, and not against the exploitation of a patent. The primary concern of the Biotech Directive is with patentability of inventions. And it is the moral aspect of an invention's exploitation that limits the scope of patentability because the issue of patenting is less about invention but about the exploitation of inventions.[192] The knowledge economy of a bio-society thrives on the exploitation of biotechnological inventions. The economic effects of such inventions cannot be invoked to restrict the field of patentable subject-matter; the EPO is only vested with the task to consider moral effects of an invention when granting a European patent for it.[193] And these moral effects must flow from the invention's exploitation. The exploitation must offend public order or morality; article 6(1) Biotech Directive and article 53(a) EPC do not raise questions of the morality of patenting a particular invention or of the morality of that invention in itself.[194]

Nor, of course, of patenting itself. The confusion of exploiting an invention and of exploiting a patent sometimes misleads the moral debate in public. No one denies that patents may have

[188] T 315/03 *Transgenic animals/Harvard* (Boards of Appeal), para 13.2.21.
[189] T 356/93 *Plant cells/Plant Genetic Systems* (Boards of Appeal), para 12.
[190] C-121/85 *Conegate* [1986], para 15.
[191] C-377/98 *Netherlands v. Parliament and Council* [2001], para 38.
[192] Rai (1999), p.97.
[193] G 1/98 *Transgenic plants/Novartis II* (Enlarged Board of Appeal), para 3.9.
[194] T 315/03 *Transgenic animals/Harvard* (Boards of Appeal), para 4.2.

moral effects besides economic ones, for example when a patent on gene sequences usable in the diagnostics of breast cancer is granted to a biotechnology dedicated company like Myriad; then patients might no longer be able to choose who is going to read and interpret their genetic information and thus become dependent on the company. This, clearly, has moral implications, but none the EPO must deal with. The potential dependence of patients on a single company results from the exclusionary rights conferred with a patent, that is the right to prevent competitors from exploiting the invention. It is the very idea of patents that their holders are entitled to exploit the patents. Hence, moral objections with regard to the exploitation of patents in biotechnology apply to the exploitation of any patent, as the possible consequences of a patent's exploitation are the same for all patents.[195]

A fundamental criticism of patents goes beyond the restriction of patentability for certain inventions. Legally, the criticism must confine itself to interpret the meaning of commercial exploitations. The Enlarged Board of Appeal allows for a rather broad interpretation when it comes to exploitations where human embryos are involved. According to the Board making an inventive product is the ordinary way to exploit an invention commercially: it must first be made before it can be used; and the making belongs to the exclusive privileges of a patent holder. Hence, making an inventive product, such as embryonic stem cell cultures, remains commercial exploitation of the invention, even where there is an intention to use that product for further research.[196] Consequently, where human embryos are used to produce embryonic stem cell cultures, the production amounts to commercial exploitation and must not be patented under article 6(2c) Biotech Directive.

The equalisation of making and exploiting expresses sensitive caution with respect to patentability in the field of human embryonic stem cells and must be seen against the economic purpose of patents in society: the Board's interpretation insinuates that any patent application for an invention implies its commercial exploitation; the inventor needs a patent only for the commercial exploitation – her prior use of the invention for other purposes is granted. Still, making and exploiting remain distinguishable within patent law, in particular with respect to morality. In a Member State the exploitation of an invention might be prohibited but not its making, and consequently an inventor may wish to produce her invention there with a view to export it to a Member State where the exploitation is not prohibited.[197] Decisive under article 6 Biotech Directive is thus the use of an invention, not yet its making.

The use of inventions falls under the jurisdiction of the Member States; it is not regulated by the Biotech Directive. Rather because the Directive is not and cannot be a compendium of morality but of patentability only, the use of biotechnological inventions has to be regulated on a national level;[198] in default of national regulations the use has to be judged against the cultural values and conventions of a Member State. Each Member State finally defines its own public order and morality – which is subject to review by the ECJ. Thus, the discretion of Member States to define public order is limited to elements which seriously threat one of the fundamental interests of society.[199] The Guidelines for Examination in the EPO, to be used at national patent authorities as well, follow a similar line of delimitation when stating that the purpose of the public order and morality provision of article 53(a) EPC is to exclude patents for innovations which are likely to induce riots, criminal acts or other generally offensive

[195] T 1213/05 *Breast and ovarian cancer/University of Utah* (Boards of Appeal), para 53.
[196] G 2/06 *Use of embryos/WARF* (Enlarged Board of Appeal), para 25.
[197] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 106.
[198] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 228.
[199] C-30/77 *Bouchereau* [1977], para 35.

behaviour.[200] In other words, there exists not much of a bar to patentability. That is not least due to the erratic appearance of morality in patent law: the refusal of a patent cannot stop immoral exploitations of an invention.[201]

2.3 Protection of knowledge

Patent protection and patentability are easily confused, like patentability and the exploitation of innovations. Contrary to what one might assume, a patent does not confer positive rights to the holder but is of negative nature. Commonly, the subject matter of a patent is presented positively and described as the warrant that the holder of a patent has the exclusive right to exploit an invention with a view to manufacture industrial products and to put them on the market for the first time,[202] and the holder has the right to litigate infringements of his exclusive right.[203] However, the exclusive right of a patent is akin more to a privilege than to a property right.[204] And the privilege is one of protection, one that protects the patent holder against the exploitation of his invention by others. It entitles the holder to prevent third parties from making, using or selling his patented invention in the territory in which the patent has effect. It does not entitle the holder to manufacture or otherwise exploit his invention. Thus, a patent confers a negative right of protection on its holder.[205]

This is expressed by recital 14 Biotech Directive which says that a patent does not authorise a holder to implement the patented invention, but merely entitles him to prohibit others from exploiting it for industrial and commercial purposes. Thus, legal limitations or prohibitions applying to the exploitation of patented products are not precluded.[206] Patents and prohibitions are not mutually exclusive. Rather, the right to exclusively exploit a patented invention is to be exercised in accordance with applicable national laws. At the end, any holder of a patent must abide by domestic regulations when he makes, uses or sells his invention. These regulations might require prior authorisation or a licence before implementing a patented innovation. Thus, the exploitation of inventions is always subject to national laws. National laws regulate for example rigorously the marketing and use of pharmaceutical products in all Member States of the EU. Drugs may therefore be exploited differently, though they are protected by a European patent.

In some cases a European patent may even be granted for inventions whose making, use and sale are prohibited by national laws of all Member States. For instance there is no obstacle to patent a type of hand weapon – no weapon of mass destruction because this would offend public order – or a copying machine that produced authentic copies in a quality such that one could no longer identify counterfeit banknotes; and it is obvious that the existence of these patents would not legalise the use of the gun or the copying machine.[207] This reflects forty years of international patent law: article 4quater Paris Convention for the Protection of Industrial Property provides that the grant of a patent shall not be refused on the ground that the sale of the invention is subject to limitations or prohibitions resulting from national laws. The rationale behind such provisions is that limitations or prohibitions may only be temporary and

[200] EPO (2010) C-IV-8.
[201] Nenow (2001), p.598.
[202] C-15/74 *Centrafarm v. de Peijper* [1974], para 9.
[203] C-350/92 *Spain v. Council* [1995], para 36.
[204] Drahos (1996), p.29.
[205] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, paras 25 and 107.
[206] C-377/98 *Netherlands v. Parliament and Council* [2001], para 80.
[207] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 26.

allow the patent holders concerned to exploit their inventions after the removal. Moreover, a Member State with restrictive national laws may benefit from the disclosure of patents when inventions whose exploitation is prohibited are the source of inventions whose exploitation is not prohibited.[208]

Therefore, patentability and protection are separate legal concepts in patent law.[209] Patentability represents the material side of patents, protection their formal side. The former determines what (kind of knowledge product) could be used for commercial exploitation, the latter determines the scope of its commercial exploitation, i.e. how far a patent holder may prevent third parties from becoming commercially active. For reasons stated below, the scope of protection may be wider than the scope of patentability. The scope of protection conferred to biological material with special characteristics resulting from the patented invention extends, pursuant to article 8(1) Biotech Directive, to any biological material derived from it which possesses the same characteristics. If the patented invention is a process to produce biological material with special characteristics, then the protection extends, pursuant to article 8(2) Biotech Directive, to any biological material obtained through it possessing the same characteristics – unless the propagation and multiplication of the biological material concerned is the marketed purpose of the patented invention according to article 10 Biotech Directive.

This genealogical protection of biological material takes into account that biological material is capable of reproduction. For the commercial value of a patent it is immaterial whether a third party produces the patented product or whether the product reproduces itself. Therefore, patent protection confers on the patent holder the right to prevent others from making use of the material's capability of reproduction and exploiting the material commercially in this way. In other words, the protection of biological material extends to its future generations. This principle is expressed in recital 46 Biotech Directive in terms of the patent holder's entitlement to prohibit the use of self-reproducing material in situations analogous to those where she would be entitled to prohibit the use of non-self-reproducing products, that is to say the production of the patented product itself. The genealogical protection thus amounts to an adaptation of patent law to the exigencies of biotechnology. It elaborates on article 5quater Paris Convention and article 64(2) EPC which require in general the extension of patent protection to products directly obtained from a process when the subject-matter of a patent is a process.

When purchasing a patented biotechnological invention consisting of biological material, the inherent reproduction mechanisms allow for unlimited multiplication of the material, in contrast to other knowledge products. A purchaser of a book protected by copyright or of a copying machine protected with a patent might resell parts of the product without any difficulty; if however a purchaser of protected biological material sold parts of it, the commercial value of the patent would because of the material's regenerative character be nullified – and with it the incentive to create innovative biological material. Because this thwarted the instrumental purpose of patents, the scope of protection is extended for biological material in order to restore patents' incentive function. A derogation from the principle of extended genealogical protection is established for farmers only under article 11 Biotech Directive with respect to the biological material of plants and animals. Farmers may use their harvest and livestock for agricultural purposes even though it is protected with intellectual property rights, but they must not use it for sale.

[208] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 105.
[209] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 126.

Furthermore, article 9 Biotech Directive extends patent protection of products containing or consisting of genetic information to all material – except to the human body – in which the genetic information is contained and performs its function. Thus, a patented gene sequence incorporated into a host microorganism extends the patent protection to the microorganism. If a patented gene sequence however is contained in a product as a residue, then the patent protection does not extend to the product. The protection of a patented gene sequence for herbicide resistance of soy beans, for example, contained in soy meal does not entail the soy meal because the gene sequence no longer performs its function in the meal. Only if and when the gene sequence resumes performance of its function, patent protection will revive.[210]

It is arguable however whether the protection under article 9 Biotech Directive is triggered when the gene sequence performs its function in general, or when the gene sequence performs the function for which it was patented in particular. Patent protection must be either substance-bound or purpose-bound. In case of substance-bound protection the patent protection covers possible future uses of the gene sequence concerned; in case of purpose-bound protection the protection is limited so that only the specific use disclosed in the patent application can be claimed against third parties. The Biotech Directive contains no limiting provisions related to a specific use which has been identified for a gene sequence. A limitation of protection may be derived indirectly alone from the limits of patentability: Because a gene sequence without determined function is not patentable, the functions not determined should not be protected; i.e. because the function of a gene sequence is decisive for its patentability, it should be decisive for its protection, too, and restrict the protection to the function disclosed in the patent application – the protection should be purpose-bound. Substance-bound protection extending to all possible functions of a gene sequence, including those not identified at the time of the patent application, would ultimately, in practice, make a mere discovery patentable.[211]

This line of argument builds on the rapid development and high level of genetic engineering. To isolate a gene sequence and to determine one function of it seems to be a matter of routine in gene labs. Against this technical background it is tempting to find the protection disproportionate when one gets protection for all functions in exchange for identifying only one function, especially if it is easy to identify one function but hard to identify more. Lastly, however, the decision whether the isolation of a gene sequence and the identification of a specific function amounts to an inventive step rests with the skilled person in the art. If the alleged invention turns out to contain no inventive step, it is not patentable; and if it is not patentable, it cannot enjoy any patent protection at all. Hence, the disproportionality of patent protection hinges on the examiner, like in all other cases. If an inventor succeeds getting a patent for an alcoholic drink, you cannot get a patent for the same liquid as a disinfectant though both purposes are different. And the same holds for gene sequences. Gene sequences considered as chemical substances do not justify a special or purpose-bound treatment as regards the scope of patent protection.

The Commission, too, cannot think of objective reasons to create a specific regime of protection for biotechnology differing from common patent protection. For the Commission the issue is an economic one related to a dynamic balance between investment in research and potential commercial reward. Empirical evidence is needed to decide, whether it is more valuable to society to limit a patent on gene sequences in scope admitting future uses of the

[210] C-428/08 *Monsanto Technology v. Cefetra BV* [2010] Opinion Advocate General, para 18.
[211] C-428/08 *Monsanto Technology v. Cefetra BV* [2010] Opinion Advocate General, para 31.

sequences concerned to be patented freely, or to allow for a broad scope of protection, so that inventors who build on such gene sequences should have to seek a licence.[212]

Whether or not patent protection shall be purpose-bound, protection under the Biotech Directive extends to any biological material derived through multiplication or propagation from biological material containing patented gene sequences. Because plants are biological material, patent protection may cover a plant variety, without that plant variety being patentable in itself.[213] This protection obviously is an intermediary between the patent protection of an isolated gene sequence and the patent protection of a plant variety with an incorporated gene sequence that could be incorporated in more than one variety. Patent protection of a non-patented plant variety relates to a patented gene sequence not yet incorporated in biological material. If however a third party incorporates a patented gene sequence into a plant, that use infringed the patent on the sequence. Without such protection a patent on gene sequences would be of little value.

A historical analogy clarifies this extended protection. Many EU Member States had prohibited patenting of drugs, whereas chemical substances were patentable. When a pharmaceutical company incorporated a patented chemical substance into a drug, the manufacturing of that drug infringed the patent. The patent protection of the chemical substance extends to the drug, notwithstanding the drug itself could not enjoy patent protection. Hence, articles 8 and 9 Biotech Directive do not mean that plant varieties themselves become patentable.[214]

A conflict between breeders and inventors is thus avoided under the current patent regime in Europe. A conflict solely may arise where plant breeders wish to purchase a plant variety for which they possess plant variety rights, however they cannot do so because a patented gene sequence is incorporated into that plant variety. In such circumstances article 12 Biotech Directive provides for compulsory cross-licensing. If the holder of the plant variety rights has applied unsuccessfully for a licence from the holder of the patent rights, and if the plant variety constitutes significant technical progress of considerable economic interest relative to that of the patented gene sequence, then the patent holder shall on the one hand be obliged to license his rights non-exclusively subject to the payment of an appropriate royalty, on the other hand he shall be entitled to a licence for using the protected plant variety in turn. These provisions on compulsory cross-licensing are embedded in the general policy of compulsory licensing in cases where the commercialisation of research results needs to resort to techniques which have already been patented.[215]

2.4 Deposition of knowledge

An isolated gene sequence becomes a patentable knowledge product when its function is determined such that the isolation or determination requires an inventive step. Because a patentable gene sequence may be identical with the sequence of a DNA existing in nature, and because gene sequences existing in nature may have different functions, i.e. be involved in cellular processes following different purposes and thus suit various industrial applications, because of that, patentable knowledge products vary in degree. One does not have to know all possible functions of a gene sequence in order to get a patent on it. For a gene patent the

[212] COM (2005) 312, p.4.
[213] C-377/98 *Netherlands v. Parliament and Council* [2001], para 46.
[214] C-377/98 *Netherlands v. Parliament and Council* [2001] Opinion Advocate General, para 126.
[215] COM (2002) 545, p.20.

determination of an adequately complex function – relative to the state of the art – is sufficient. The gene sequence has to perform a function which answers its industrial applicability. On top of that, the description must be clear, not only with regard to the function but also with regard to the gene.[216] The technical pragmatism of patentable knowledge products is reconciled with the classical criterion of clarity.[217]

The more of a gene sequence is disclosed, the more clear the knowledge about it becomes. The promising knowledge economy however would not get off the ground if one had to wait for full clarity before patenting and exploiting the biological material concerned. Biological material being the substance of biotechnological inventions favoured by the promoters of knowledge economy in Europe is supposed to become economically most effective when the disclosure requirements are comparably low. Thus, article 13(1) Biotech Directive and rule 31 EPC allow for a deposition of biological material in place of a description if the biotechnological invention cannot be described in such a manner that a person skilled in the art is able to reproduce it. The deposition of the material is then regarded as being disclosed. Whatever its economical effects, the depository provision that is specific to biotechnology patents further complicates patent law.[218]

The gradual disclosure requirement is bound and relative to the knowledge of the ideal person skilled in the art, a knowledge which is not always easily identified because it is a capacity to be exercised and no database to be read out. Prior art disclosures of gene sequences change over time as science advances, and scientific progress raises, in principle, the level of the inventive step required for patentability. The EPO however demands in opposition procedures a high level of prior art knowledge, and thus a comparably low level of individual inventive achievements: In order to successfully oppose an invented gene sequence deposited at a gene bank as being merely state of the art, the applicant has to demonstrate a published knowledge of the sequence detailed down to the position of the relevant (mutated) nucleotide.[219]

As to the availability of biological material a sample shall be supplied to anyone requesting it after the application had been published according to rule 33(1) EPC or after the patent had been granted according to article 13(2) Biotech Directive respectively; up to the publication only persons authorised under national patent law shall have access to the deposited material. The material shall be supplied only, pursuant to article 13(3) Biotech Directive and rule 33(2) EPC, if the requester has undertaken not to make the biological material or any material derived from it available to third parties and to use that material for experimental purposes only, unless the applicant or holder of the patent expressly waives such an undertaking.

The primary function of a biological material deposit is to complete an otherwise insufficient written disclosure.[220] The conditions of a sufficient disclosure depend on the knowledge of the skilled person in the art. The knowledge of this person however is the unknown in the procedure, it is the dark horse of patent law that has to be circumscribed from case to case. An invention must be disclosed clearly enough that the skilled person can reproduce it. In the field of biotechnology, reading a patent application must enable the skilled person to reproduce a given biological material or, as an alternative, to obtain the material from biological material containing it, if a deposit of such material had been made with a recognised depository bio-

[216] T 1165/03 *Soybean transformation/Monsanto* (Boards of Appeal), para 16.
[217] Peirce (1968), p.62.
[218] MacKenzie (1990), p.69.
[219] T 666/05 Mutation/University of Utah (Boards of Appeal), para 5.
[220] G 2/93 *Culture deposit information* (Enlarged Board of Appeals), para 8.

bank.[221] The deposition facilitates patenting in two ways. First, it allows patents for non-conceptualised knowledge products; and second, it simplifies the disclosure requirement under article 83 EPC: the skilled person can simply request the biological material and thus obtain it without undue burden.[222] Hence, when it comes to patents in biotechnology the prompt certification of knowledge with patent rights often is at the expense of its clarity; it need not even be clear how it can be derived from material deposited, the main thing is that the skilled person can derive it from that material.

[221] T 29/06 *Bordetella/Aventis* (Boards of Appeal), para 2.
[222] T 549/05 *Aspergillus niger/Da Barra* (Boards of Appeal), para 5.

3 Knowledge as production factor in economy

The Biotech Directive is one of the EU's instruments within the European patent regime giving effect to its instrumental knowledge policy. The major political rationale behind the expansion of patentability to biological material is to facilitate economic growth through stimulation of innovating activities. Whether patents are an appropriate instrument to achieve the economic policy aims, particularly in the biotechnology industry will be discussed in this chapter. The discussion takes place against the background of an emerging knowledge economy where high-tech knowledge products and respective intellectual expertise are established as vital production factors for the performance of an industry. In the EU's concept of knowledge economy creative expertise is discriminated against imitative expertise; in other words, the capacity to invent is more valuable than the capacity to reproduce, or innovation is more valuable than reverse engineering. In patents this discrimination becomes visible – and enforceable. No less than the justification of such discriminatory treatment of knowledge is at stake when discussing the substance of the policy argument that patents stimulate innovations.

The argument will be approached both from a theoretical and a practical perspective. Theoretically, the availability of indicators will be explored that could demonstrate innovative growth effectuated by patents; and it will be explored how patents fit in the economics of innovation – rather imperfectly as it turns out. The imperfect economic conception of patents leaves us practically with elementary facts observed in relation with patents. Instead of representing functional interdependencies between patents and economic activity, the observed facts rather deliver the building bricks for an economics of patents which opened the balance of a patent system's costs and benefits for society. A future economics of patents would have to explain the patenting behaviour of companies and their use of patents as strategic tools as well as their use of alternative tools to appropriate returns on innovations, which here can only be reported.

Observed facts like the emergence of patent warfare with patent arms race and deterrent lawsuits concerning the validity or infringement of patents suggest detrimental effects of patent regimes; at least the costs of patents seem up to now more easily ascertainable than the promised benefits. Due to the lack of a comprehensive economics of patents, the assessment of a patent regime, however plausible, remains preliminary.

The preliminary results gathered from elementary facts with regard to patents' impact on innovation will finally be applied to the biotechnology industry where benefits resulting from patents are said to prevail over costs. But evidence taken from the kind of patents and the use of patents does not support this assumption: What is patented to what purpose in biotechnology industry does not differ significantly from other branches of industry. Taking together all the evidence brought forward in this chapter, the argument finally that patents are an effective incentive that stimulates innovation can hardly be upheld on economic grounds.

3.1 Economics of patents

The patent economics of interest in this work is delimited by the knowledge policy of the European Union. The economics of interest thus concerns stimulating innovations and disseminating the underlying knowledge. Hence, economic considerations of the savings achieved by having one European patent instead of twenty-seven national patents are excluded here, as well as considerations of markets genuinely created by patents, such as the legal and technical services surrounding the trade and enforcement of patents, or the additional income through licensing; these considerations are excluded here even though Member

States of the European Union are among the very few countries worldwide who earn more money from licenses than they must pay for them.[223]

The instrumental knowledge policy of the European Union has as its primary aim reducing a shortage of new technologies by inducing more investments in innovation.[224] Patents are thought to be incentives to invent: they offer a twenty years protection of an invention in exchange for disclosing the knowledge of how the invention works. This knowledge might be used by others to improve on the patented invention and to come up with new inventions to be filed again at a patent office, so that Europe does not run short of new technologies. The value-added chain of patents put simply means that patents induce investments in innovations, investments in innovations lead to technological inventions, and technological inventions result in economic growth and social welfare. That is the political idea, but does it correspond to the economic reality?

In order to determine the economic effects of patents with regard to investment and innovation the respective key figures and main characteristics must be outlined against which the effects can be measured such that it could finally be decided whether the European Union is achieving its policy aims in the field of biotechnology. A first hint to the EU's chances of success should be given by the extent to which the European knowledge policy fits within the economics of innovation.

3.1.1 Main characteristics and key figures of patents

Following the value-added chain of patents one must distinguish characteristics indicating investments induced by patents, and characteristics indicating innovations that go back to patents. The former indicate the effectiveness of patents in attracting money for research and development; the latter indicate the effectiveness of patents in generating new valuable ideas. So far the theory; in practice however reliable indicators to measure the effects of patents are lacking completely. Compared to other areas of economy where economic indicators are widely available, the measurement in the area of patents is at a very crude stage.[225]

Most common if anything are indicators for the investment in research and development. Such indicators are in the sector of biotechnology human resources devoted to biotechnology, stock of biotechnology human resources, public spending, venture capital, or the number of biotech start-ups.[226] Hence, the monetary and human capital invested in innovation can be measured to a certain degree, and indeed appears under the given indicators in recent statistics. The effect of patents could be inferred roughly from comparing investments in biotechnological research before and after 30 July 2000 when the Biotech Directive became effective in the Member States.

When it comes to the knowledge-based innovativeness of an economy, common indicators have to be established yet. Clearly, one cannot equate patents with innovations and then simply count the patents granted to persons of the Member States.[227] Such an oversimplified measurement would be skewed because many research-based innovations are not patented, and some patents may not be based on research and development. The analysis of patent

[223] Beer (2008), p.127.
[224] Guellec (2007), p.53.
[225] Gambardella (2006), p.ii.
[226] Pattinson (2000), p.138.
[227] Carlsson (2000), p.25.

citations, i.e. the analysis of references to patents in patents indicates the technological importance of an invention; however, the implied economic value remains relative to other patented inventions.[228] Patent citations thus may identify the most important inventions and track the decline of a patent's importance over time, but they do not indicate the innovative status of an industry, and thus do not allow inferences to improvements with regard to the quantity and quality, or societal value of inventions.

Therefore, one has to find a more sophisticated approach to the difficulty of specifying reliable innovation indicators which then could trace back innovative progress to patents. Now, in liberal economies the market is deemed to be an incorruptible indicator of economic values. These values are measured in market prices. Because markets have a supply side, a demand side, and a competitive side, all three sides might guide to reliable indicators of innovation.

Starting point for an approach to indicators of innovation must be that patents have different values. The difference now might be evaluated by patent holders, by consumers or by competitors. Internationally it can be assumed, that an inventor would seek patent protection for her most valuable inventions on the most important markets. These are, in particular with respect to the enforceability of patent rights, the United States, Japan, and the European Union. A patent granted at the United States Patent and Trademark Office, the Japan Patent Office, and the European Patent Office thus indicates a superior value of that invention compared to less widely patented inventions. Such triadic patents[229] possess for the inventor a special value which in turn can be quantified. A measure of the value of a patent then is the minimum price at which the patent holder would be willing to sell the patent at the moment in which it is granted. This indicator is called patent premium.[230]

For most innovations the patent premium would be negative, if one charges the minimum price of sale up against the patent fee. That is one reason why many inventions are not patented.[231] For patented inventions in Europe the respective patent premium is quite high and sums up to several million euros on average.[232] However, a small number of patents accounts for the lion's share of the overall economic value of patents; that is, most of the patents are worth very little, while only a few have very high value. But not only a few inventions benefited thus from patent protection, the evaluated value of patents is rather volatile and idiosyncratic, too. It depends on the existence of alternative technological inventions, or on the contingent behaviour of consumers.

The consumers then lead over to the demand side. On this side the value of a patent is indicated by the value of the patented invention. In other words, the value of a patent is indicated by the market price of the patented invention. The market price is the maximum price at which consumers are willing to buy a certain quantity of that patented invention. Of course, the market price is even more volatile and idiosyncratic than the patent premium, because it can change suddenly with a shift of consumer preferences, for example when a superior technological invention appears on the market. In general, the turnover of patented inventions to market prices lies significantly below their patent premium. Patents double on average the value of an invention for the patent holder.[233]

[228] Trajtenberg (2002), p.25.
[229] Guédou (2007), p.2.
[230] Gambardella (2006), p.4.
[231] Guellec (2007), p.70.
[232] Gambardella (2006), p.4.
[233] Guellec (2007), p.70.

On the competitive side finally, it is the competitors of an inventor who indicate the value of a patent. Competitors try to hinder each other from introducing inventions that very likely diminish the market share of a competing product. Hence, a competitor will on such occasions sue the inventor for an infringement of his own patent or he will oppose the invention denying its novelty. Competition thus explains why litigated patents tend to be more valuable patents,[234] but litigation itself hardly amounts to an adequate indicator of innovations, already because substantive inventions embodying considerable technological progress are not challenged before a tribunal.

3.1.2 Market doctrines of innovation

So far the analysis of innovation focussed on indicators for successful innovations, it omitted however indicators for missed innovations. Economic patent analysis often pays attention exclusively to innovations which were made, and thus leaves out the economically highly relevant reasons for failed inventions.[235] Since patents could as well hamper innovations, rather than stimulate them: knowledge not only permits – it also constrains. Patents may for example concentrate investment in certain economic sectors, withdrawing money from other sectors where inventions then become less likely; or patents may impede innovation by prohibiting innovative combinations of protected inventions because of patents' exclusivity: third parties are not allowed to make use of a protected invention without the authorisation of patent holders. [236]

Such negative indicators pointing to impeded innovations can only be developed in a comprehensive economic theory of innovation, and then be opposed as patent costs against the positively indicated patent benefits.[237] Related to the costs of impeded inventions are the costs of simultaneous inventions. These costs consist in the circumstance that the first to file a European patent for the respective invention has the exclusive right to prevent others from commercially exploiting the invention, even if they made the invention simultaneously or otherwise independently. This strict prevention is in principle mitigated only in case of proven prior use.[238] The patent regime thus denies the inventors and consumers the benefits of independent inventions, a denial that equalizes sunk costs for the inventor and a deadweight loss for society due to the lack of price competition.[239]

Patents do not only provide opportunities for economic growth, they also restrict these opportunities. The final balance of patents' costs and benefits for economy rests more stable on the costs than on the benefits, because most of the costs can be identified more easily; such as the investment costs for research and development, the transaction costs for fees of patents and licenses, or the development costs for sustaining the whole patent system of examining, granting, supervising, and enforcing patents.[240] Only the calculation of creativity costs for impeded or delayed innovations because of patents confront economists with difficult problems on the cost side of the balance.

234 Hall (2007), p.571.
235 Rosenberg (1974), p.106.
236 Hall (2007), p.572.
237 Posner (2002), p.12.
238 Neukom (1990), p.165; Gallini (2002), p.147; Shapiro (2004), p.1045.
239 Boldrin (2008), p.206.
240 Rai (1999), p.136.

A considerable cost of patents has become litigation costs. In the pharmaceutical sector alone the number of patent litigation cases increased by a factor of four between 2000 and 2007. Each year up to two thousand cases concerning the infringement or validity of patents are raised before the first instance tribunals of the EU's Member States. About 70% of these cases concern European patents.[241] Because of litigation costs and the lawsuits' uncertain outcome (in about one tenth of the final judgments regarding patents on drugs two or more different courts in different Member States give conflicting rulings on the same issue of patent infringement or validity)[242] most of the patent related conflicts are settled before it comes to litigation. In case of litigation the aggregate legal costs of all parties end up in several million euros for one trial at one tribunal, depending on the value of the patent. If a company does not have that financial backbone to look credible in patent defence, there is little economic point in filing patents in the first place.[243] In the end, only chemical and pharmaceutical multinationals make today higher profits with their patents than they face litigation costs to alleged infringements or invalidities.[244]

As it seems to turn out, a patent regime induces only in a few countries on a few sectors for a few inventions considerable economic value. It appears that the full-fledged patent system just serves blockbuster drugs invented in the United States, the European Union, and Japan. Then the patent regime would have highly specific effects, restricted to the chemical and pharmaceutical industry of developed countries. These specific effects are clearly not reconcilable with the EU's policy aim of stimulating innovation by patents for the whole knowledge economy of the internal market. In this respect, the Commission argues that the opportunities provided by patent law are not yet exhausted, and that complementary factors not related to patents hinder such an exhaustion, for example insufficient supply of venture capital or shortcomings in the cooperation of science and industry.[245]

Such arguments can only be assessed within the economics of innovation where patents must find a fit. The economics of innovation should be able to explain how patents contribute to social welfare. When having ascertained these benefits of patents theoretically, the account might be opened of a balance weighing their costs and benefits. From the outset however it cannot be taken for granted that patents necessarily lead to more innovation, which strengthens an economy's competitiveness and raises there the standards of living.[246] Rather it will be seen which functions are attributable to patents in the economics of innovation.

Classical economics of innovation assumes an incentive function for patents.[247] Patents stimulate inventions because they reward inventors with a legal monopoly. A legal monopoly allows the inventor to prohibit anybody else the industrial production and marketing of her patented inventions. The patent holder alone has the right to do so. In principle, then, a legal monopoly leads to an economic monopoly. An economic monopoly allows the monopolist to sell her patented inventions above marginal cost, i.e. above the cost she has to incur in order to produce an extra unit of the invention. In a full competitive market marginal cost equals market price, because a company will go on producing extra units as long as it achieves a price for a product which lies above its production cost. When the production cost for an extra unit becomes higher than the achievable market price, a profit maximising company restricts

241 Adelman (2009), p.638.
242 European Commission (2009), p.11.
243 Bains (2009), p.65.
244 Bessen (2008), p.16.
245 COM (2007) 175, p.8.
246 Levin (1987), p.787.
247 Arrow (1962), p.619.

its production output. Pricing above marginal cost thus means superior profits for a company, which is why being endowed with a monopoly amounts to a lucrative incentive for investors who seek a maximum return on their investment.

The problem with the incentive function of patents is that no relevant monopoly based on patent protection exists anymore.[248] The disappearance of monopolies is due to the proliferation of the global market with imperfect substitutes. In particular technological products display a rich facet of features and are seldom identical. One product may be superior to others in one feature but inferior in another; or one product may have less or slightly inferior features than other products but still remain saleable because of its lower price. A legal monopoly therefore does not imply an economic monopoly. But as patents do not confer monopoly market power to the patent holder, patents can hardly be deemed to be economic incentives. Rather, companies strive for monopolies on the market, but they do so without a need for patents.

Myriad, holding the patents for BRCA1 and BRCA2, did not have an economic monopoly on the diagnostics of breast cancer but tried to build one on its legal monopoly. It did so by trying to establish the genetic testing of breast cancer as the gold standard in diagnostics against existing alternatives.[249] Myriad centralised genetic breast cancer testing and required that the samples of gene sequences from risk individuals were sent to a sister company for the test. The company then got for free the main research material concerning further discoveries of genes coding for breast cancer which Myriad would file in further patent applications and thus strengthen its market position for the diagnostics of breast cancer towards a monopoly.[250]

Such a monopoly is what competitors of Myriad and other potential monopolists watch not to emerge. And the most successful means to prevent competitors from becoming monopolists are superior inventions. Competitors have to invent something in order to compete with a monopolizing invention; either a new product that could be regarded as substitute or a new technology that reduces production costs and allows for price advantages of the product on the market. A company which is not continuously innovative simply loses market share and is finally squeezed out of the market. Innovation on competitive markets has become routinized.[251]

On competitive markets patents play little role at the pioneering stage of an industry: The incentive to share knowledge between competitors is very strong, because sharing increases the chances that further innovations follow which drive the industry forward to stages of marketability. Competitors publish small intermediate steps towards a desired invention, encouraging others to make additional advances.[252] At these early stages of an invention secrecy proves ineffective, because the intermediate innovations can be easily identified and the likelihood of independent invention is high.[253] Not until the aspired invention comes in reach, cooperative sharing breaks off and the desperate race to be the first on the market is on; each further step is kept secret henceforth. When finally the invention is made and the creative reservoir of the first mover runs dry, patent protection becomes desirable for the company.[254]

[248] Scheffler (1989), p.801.
[249] Belt (2004), p.26.
[250] Gaudillière (2009), p.24.
[251] Baumol (2002), p.4.
[252] Boldrin (2008), p.136.
[253] Rai (1999), p.119.
[254] Guellec (2007), p.43; Boldrin (2008), p.43.

Hence, on competitive markets patents could fulfil a protective function that shall sustain competition between innovating companies.[255] The core argument of this doctrine is that patents should protect innovating companies from free-riders. If free-riders could freely make use of the innovating companies' inventions, they saved the investment cost for research and development. Assumed that the costs for reverse engineering an invention are lower than the costs for research and development, free-riders faced lower minimum marginal cost for the same product and thus gained cost advantages they can transform into higher profits than any of the innovating companies. For the latter, in other words, investments in innovation would not give good returns, and competition on behalf of new and better products was distorted. [256]

The doctrine of patents' protective function suffers from two deficits. First, it requires that any company achieves to get patent protection for any of its inventions, because else free-riders could sneak in any moment and replace innovating companies on the market. This requirement is not only far from realistic, it is also not competition conducive in terms of slowing down innovative market processes which gain speed instead when intermediate inventions are shared openly. Second, the doctrine assumes that at least most of the competitors always succeed to innovate something different that allows them to remain competitive. For this assumption, however, there is little evidence.

In sum, neither the incentive function nor the protective function can be convincingly integrated in the economics of innovation. Patents do not necessarily make a competitive market, stamped by routinized innovations, more competitive or innovative. Nor can from a theoretical point of view be concluded that patents effectively hindered competition or innovation, since patents still might induce a stronger competition based on innovation through ensuring the disclosure of knowledge which competitors may use freely to improve on patented inventions, and which would be kept secret without patents. For such a disseminative function of patents there exists no economic doctrine yet. The economic connection between patents and innovation remains an article of faith.[257]

3.1.3 Elementary effects of patents

Because of the lack of any conclusive economic doctrine concerning patents' function in a competitive knowledge economy based on innovations, the effects of the European patent regime cannot be measured against a theoretical standard but must stand on its own. Evaluated outside any economic theory, the assessment of patents' effects on industry cannot be but preliminary and has to await a comprehensive theoretical outline which enabled to account for a total balance of patents' costs and benefits. Insofar the effects are not integrated into any economic theory it will be talk of elementary effects. These elementary effects seem to be none of enhanced investment in innovation, and none of enhanced innovation output either.

With regard to innovation output, recent studies by economists did not succeed in establishing a systematic link between patents, research and development, or innovation.[258] The studies did not reveal any evidence that strengthening patent regimes increased innovation output; however they revealed that strengthening patent regimes increases patent output:[259] instead of

[255] Pretnar (2004), p.780.
[256] Reichman (1997), p.12.
[257] Beer (2008), p.9.
[258] Beer (2008), p.127.
[259] Boldrin (2008), p.192.

more inventions the regime bestows more patents on society. The sheer number of patents does not indicate brisker innovative activities, or a wider supply with inventions; it does not even indicate the inventors' presumed intention to exploit the protective function of patents in sustainable competition. It is the value of a patent that is relevant for an economy – be it from the perspective of suppliers, consumers, or competitors; but that value cannot be derived from the sheer number of patents because patents differ in value.

The increasing number of patents causes more concern than enthusiasm with regard to the innovation process. Patents intensify a patent thicket in which potential inventors and investors can no longer see all patent holders from whom they needed licenses in order to realize an invention related to or based on patented inventions. In economic terms, singling out of the patent thicket the relevant patent holders, and bargaining a licensing agreement with each of them separately, raises the transaction costs considerably. These costs may deter investors and deprive society of beneficial inventions. Thus, the eager patenting induced by the patent regime may lead to an underuse of available knowledge. Because patents privatize knowledge-based products making it an excludable commodity, and because the potential underuse stands in opposition to the overuse of commons, this phenomenon is referred to as the tragedy of the anti-commons.[260]

This tragedy becomes even sadder when some or only one of the multiple patent holders makes use of the patent right to exclude others from making use of needed inventions. With a patent in the pocket you can bluntly veto down innovative projects which integrate that patented invention. Given the surpassing proliferation of patents in biotechnology and the thicket originating from the fact that very many, if not almost all biological processes of an organism are interdependent, an exclusive use of patents on biological material may paralyse whole branches of the biotech industry. This might be an extreme scenario, and indeed a survey of academic and commercial researchers in the area of biotechnology could not identify one case where research would have been cancelled due to the problem of the anti-commons.[261] Another study analyzing the citation rate of scientific publications reports only slight anti-commons effects.[262]

However, delays instead of frustrations of research projects can very well be traced back to the problem of the anti-commons. Licensing problems delayed the development and marketing of beta-carotene enriched, genetically modified rice for several years. The Federal Institute of Technology Zurich, where the 'golden rice' has been developed in order to fight hunger and malnutrition in the tropics, had to deal with as many as seventy patent claims related to the gene transfer techniques which the scientists needed to produce the genetically modified rice. One can then imagine the potential delay of the development of a diagnostic test for cystic fibrosis, a lethal metabolic disorder, to which over 600 mutations are related, if different biotech companies held a patent on each of these mutations.[263]

The outlook on innovative blessings of patents, then, is overshadowed by patent thickets. And retrospection neither clears away the upcoming pessimism. Historically, states without patents were just as innovative as those that had patents.[264] In Italy, patents on pharmaceutical products were prohibited until 1978. Despite the absence of any patent protection, Italy had developed a strong pharmaceutical industry which was ranked worldwide as the fifth-largest

[260] Eisenberg (1998), p.698.
[261] Guellec (2007), p.77.
[262] Murray (2007), p.2.
[263] Resnik (2001), p.50.
[264] Bessen (2008), p.13.

producer and seventh-largest exporter of pharmaceuticals. After the introduction of a patent system, the Italian pharmaceutical industry did not perform any better, the development and export of new drugs did not increase.[265]

What increased instead is the potential damage of a prolonged exclusion from making use of a new drug or any other invention. Patents offer inventors an opportunity to exclude others from using an invention in addition to secrecy. Within a patent system an inventor will choose secrecy when it is possible to keep the secret for longer than twenty years, and she will use patent protection when the secret can be kept only for less than twenty years. In other words, where competitors can be excluded from using an invention for more than twenty years, they still remain excluded for the maximum length of time; and where competitors could be excluded only for a shorter time, they are now excluded for twenty years.[266] The disclosure gain is zero, and a competition based on disclosed knowledge does not get off the ground. Only knowledge that cannot be hidden for long is revealed by patents earlier to the market than competitors needed time to find it out for themselves. How far market competition benefits from such marginal head start remains speculative as long as adequate economic evaluations owe to be carried out. The benefits certainly need not be marginal in an ever intensifying knowledge economy.

Anything but speculative is the statement that the expansion of the European patent regime both in terms of patentable subject-matter and enforceability through Directive 98/44 on the legal protection of biotechnological inventions and Directive 2004/48 on the enforcement of intellectual property rights effected a considerable increase in patents filed[267] and granted.[268] Along with the patents granted the premium patent has increased and even outpaced the growth of the gross domestic product between 2000 and 2002; in a like manner the number of patents filed has outpaced the investment rate in research and development.[269] These findings suggest that the increase in patenting is rather an autonomous affair of the patent system than a sign for intensified innovative activity; in fact, patents do not proportionately attract investments in research and development when their number grows faster than research and development. Hence, economic studies neither link patents sufficiently to innovation nor to investments in innovation.

The thriving patents-generating patent system does not only come up with raised patent premium. The increase in patenting also has been roughly paralleled by an increase in patent litigation.[270] The raising number of infringement and validity procedures should be less correlated with the raised patent premium, because only a few patents account for the measured growth; it is rather correlated with the quality of the patents. The quality of patents is attached to the percentage of invalidity cases, i.e. the percentage of patents that have to be revoked. Clearly, this percentage heavily bears on the design of patent applications. For companies only disclose in their applications what is necessary to get the patent granted.[271] This implies that applicants no longer report the state of the art related to the alleged invention.[272] It goes without saying that patent applications designed in such a manner make their examination extremely difficult, in particular when one considers that the examiner must

[265] Boldrin (2008), p.216 and 222.
[266] Boldrin (2008), p.166.
[267] Gurry (2007), p.257.
[268] Overwalle (2009), p.416.
[269] Gambardella (2006), p.28.
[270] Hall (2007), p.571.
[271] Beer (2008), p.136; Boldrin (2008), p.253.
[272] Osterrieth (2009), p.541.

not only go through English and Japanese journals but incrementally also through Korean, Hindu and Chinese patent publications to fully capture the state of the art. The unbound proliferation of publications makes it on the other hand for competitors quite easy to find a publication which can be used to oppose a patent application before a tribunal, if not on the basis of lack of novelty then on the basis of lack of an inventive step.[273]

A further trend in patent applications that promotes litigation is to claim as claim can. With excessive claims the applicants try to cover whole fields of technology, from which they can exclude their competitors once the applicants got their patent granted. Excessive claims are made in scope, in number, and in detail. Harvard University first tried to get a patent on animals when filing the onco-mouse, then tried to get one on rodents, and finally ended up with one that restricted the scope on mice. Besides, applicants put ever more claims on their applications. Between 2000 and 2005 the number of claims in applications before the European Patent Office has doubled.[274] And these claims are spread on an ever growing number of pages. To date applications of over 1000 pages are frequently filed at the European Patent Office; several applications have even reached 100 000 pages covering up to 20 000 claims.[275]

A final feature of current patent applications is vague wording.[276] Words printed in a patent document that could mean all or nothing subject technology investors again to an unavoidable risk of litigation. Vaguely or overly abstract worded patents try to hide claims they can bring into position against disagreeable competitors when necessary. Thus, the patent system can be a minefield for investors where they have to reckon at every inventive step with a costly infringement procedure.[277] If however the risk of inadvertent infringement is too great, the net incentive of patents to invest in innovations becomes negative. The threat of litigation seems at least in certain areas of biotechnology to discourage investors to invest in biotechnological research and development.[278] Patents then would adopt a disincentive function rather than an incentive function.

In concluding, the number of litigations is a poor indicator for patent induced innovation, too. The remarks on infringement and validity procedures point up that companies have adapted to the patent system and make use of patents as a tool of company strategy. It is however questionable whether the strategic uses result in an increase in innovative activity; at least an innovative activity that goes beyond innovative uses of patents.

3.2 Strategies to exploit patents

A straightforward company strategy is to seek protection with a patent application. A company's willingness to file a patent application may however conflict with its simultaneous wish to disclose the results of its research and development as quickly as possible to the scientific community, to investors, or even to its competitors when the results belong to the early stages of an invention or a developing branch of industry. Because it usually takes up to eighteen months until a patent application is published, the adoption of a protection strategy conflicts with the publication strategy and may hinder the rapid dissemination of knowledge,

[273] Scheffler (1989), p.799.
[274] Guellec (2007), p.210.
[275] Hall (2007), p.580.
[276] Bessen (2008), p.9 and 19.
[277] Nenow (2001), p.586.
[278] Lerner (1995), p.494.

thereby slowing down technological progress. Article 93(b) EPC however allows for earlier publication at the request of the applicant. Consequently, only a very small fraction of researchers in biotechnology experience a remarkable delay in publication of research results which form the subject-matter of a patent application.[279] The effective delay of publication is deemed to be somewhere between five and ten percent.[280]

The protection strategy and the publication strategy are the fundamental strategies the European Union envisages for its patent regime. It is the protection that shall act as an incentive for investors and attract investments in research and development; and it is the publication that renders possible a wide dissemination of knowledge. In the context of increased litigations related to patents however the applicants' behaviour hinted already at additional strategies companies pursue within a patent system. To understand these strategies actually deployed by companies a small typology of patents might be helpful.

3.2.1 Kinds of patents – a typology

A patent, to begin with, is an official document issued upon application which describes an invention and creates a legal situation for a limited period of time in which the patented invention can usually only be exploited with the authorisation of the patent holder.[281] A patent holder's legal privilege to exclude others from exploiting the patented invention expires twenty years after the date of filing of the patent application according to article 63(1) EPC.

An *evergreening patent* prolongs the term of protection to an indefinite period of time by cumulating ever new patents for essentially the same invention. An evergreening patent consists of an unbroken sequence of patents for inventions that differ only in minor amendments. A pharmaceutical company thus may keep patent protection on a medical substance sine die when converting for example a base into a salt and filing a patent application for the salt before the patent on the base expires.[282] The European patent regime facilitates evergreening patents insofar as a pharmaceutical company may additionally invent a biotechnological process to produce a substance for which it holds a patent that is about to expire, patent the process, and enjoy the protection extending to the substance under article 8(2) Biotech Directive for another twenty years.

Evergreening patents evade the prohibited *double patent*. A double patent means the grant of two patents for one and the same invention to a single inventor. According to the Enlarged Board of Appeal an applicant has no legitimate interest in proceedings leading to the grant of a second patent for an invention she already holds a patent on.[283] Hence, amendments are to be refused by the European patent office, if they finally claim the same subject-matter as a patent already granted or as an application still pending, what may happen in divisional applications under article 76 EPC.

A *divisional patent* is part of a consortium of patents related to one invention which covers several inventions. A divisional patent results from the principle of one invention – one patent. The unity of invention, as stated under article 83 EPC, requires that the patent applica-

[279] COM (2002) 2, p.4.
[280] *Association for Molecular Pathology v. United States Patent and Trademark Office* 09 Civ. 4515 (S.D.N.Y. 2010) 70.
[281] WIPO (2006), 7.1.
[282] *Novartis v. Union of India and others* (High Court of Judicature at Madras 2007), p.34.
[283] G 1/05 *Divisional/Astropower* (Enlarged Board of Appeal), para 13.4.

tion is related to one invention only or to one group of closely linked inventions. If an application lacks unity of invention, the applicant has to split the application into several applications: the invention is divided into its compound inventions and the parent application dissociates into divisional applications, for which the applicant gets a divisional patent. Divisional applications are filed under article 76 EPC and shall be deemed to have been filed on the date of filing of the parent application. The divisional application is principally independent from the parent application and the divisional application is treated as a new application.[284]

Divisional patent applications cannot extend the content of the parent application nor the protection term, but they could prolong the examination period of an invention at the European Patent Office indefinitely, because the examination of divisional patents continues even if the parent application is withdrawn or revoked. This prolongation contributed to a temporary extension of legal uncertainty with regard to competitors who are ready to enter the technology field of the invention under examination. For this reason rule 36(1) EPC sets a time limit for the application of divisional patents of twenty-four months from the Examining Division's first communication in matters of the parent application.

A *blocking patent* focuses on the exclusion of competitors without pursuing innovative efforts. Hence, the holder of a blocking patent does not produce or market the invention himself nor does he license the patent rights to generate royalties. If the patent holder aims at excluding his competitors from exploiting an invention commercially, i.e. blocking them from entering a certain market,[285] the blocking patent might be called *offensive patent.* If a blocking patent is used to demonstrate the ability to sue or counter-sue potential or aggressive competitors, it is called a *defensive patent.*[286] A rich portfolio of blocking patents allows its holder to defend himself in case of patent litigation, as it is quite likely that the appellant in turn infringed one of the defendant's patents. Thus, in the emerging patent litigation warfare blocking patents might serve a defensive patent equilibrium. In this tension between offensive and defensive use of patents, companies arm themselves with blocking patents, in particular large companies,[287] because in an intensified knowledge economy yet a preliminary injunction is a predatory weapon in patent cases.[288]

An *ambush patent* completes the patent weaponry of companies. An ambush patent is held by a company who is participating in sessions of standard-setting organisations, where it does not disclose its patents or pending patent applications, but instead influences other participants, or modifies its patent applications such that one of its patented technologies becomes an industry standard. As soon as the technology has become an industry standard the cheating company collects royalties from its competitors who cannot avoid but pay them.[289]

A *fooling patent* deliberately disorients competitors. The knowledge disclosed in a fooling patent creates a smoke screen over a company's real innovative activities;[290] it pretends that the company will exploit the patented technology and lures competitors into the wrong track of the race for an aspired invention. It does so because competitors regularly study the published patent applications of their rivals in order to be informed on progress in the field and to strengthen their absorptive capacity.

---

284 G 4/98 *Designation fees* (Enlarged Board of Appeal), para 5.
285 T 339/93 *Modified vaccinia virus/Health Research* (Boards of Appeal), para v.
286 Beer (2008), p.160.
287 Gambardella (2006), p.13.
288 Boldrin (2007), p.74.
289 Fischmann (2010), p.185.
290 Guellec (2007), p.87.

A *sleeping patent* finally is left completely unexploited and fulfils no purpose in the competition of companies based on innovations. Sleeping patents typically arise as by-products of a company's research and development activities.[291] Now that we know the name of the tools, we can turn to their implementation in companies' strategies on competitive markets.

3.2.2 Exploitation of patents

Companies exploit patents far beyond the conferred privilege with respect to the production and marketing of inventions. Patents have become an integral part of knowledge economy and thus shaped the competitive manifestation of that economy. The patent regime cannot be reduced to the triad of inventing, patenting, and producing (or licensing). Companies have been transgressing these puritan boundaries for a long time. Their reasons for patenting are manifold and sometimes more innovative then the patented invention. For companies the prevention of competitors from selling like products is only slightly more important than the availability of assets for defence purposes.[292]

Defensive patents have achieved a high status in knowledge economy, because companies tend to consider litigation as a signal to deter competitors or potential market entrants, and not so much as a means to enforce infringed patent rights.[293] Litigation, or more precisely the attached costs to it, signifies the willingness to exert financial pressure regardless of the merits. The unmistakeable message to a competitor is: whenever your product resembles our product to the extent of becoming a potential substitute, make sure to include litigation costs in your calculations, because we have patents enough to hunt you crisscross the whole market! Only a large bundle of defensive patents might impede the lawsuit chase signalling that the other's product very likely overlaps to the protected rights of the defensive patent holder. The costs for reaching such a defensive patent equilibrium sure means an extra burden for innovative companies.

While aggressive competitors exert pressure with offensive patents and even aim at blocking others' research and development, innovation-oriented companies seek with defensive patents to hedge a scope for innovative manoeuvres.[294] The patent regime thus implies that companies with innovative ambitions have to buy their market sector with patents that fence in the knowledge defining this sector, within which they can exploit their expertise in research and technologies, without being hampered by nasty companies who play out patents whose only purpose is to hamper competitors. The evidence of such strategies substantiates further the criticism that the patent system backfires in the economic reality.

Arguably as momentous as defensive patents are evergreening patents in the pharmaceutical industry. Pharmaceutical companies use any available trick to extend the commercial life of their drugs.[295] A legal extension of patent protection for drugs is allowed for under Regulation 1768/92 concerning the creation of a supplementary protection certificate for medicinal products. The regulation takes into account that the authorisation process for a drug consumes much of the protection term of a patented drug. The protection term starts pursuant to article 63(1) EPC with the filing of the patent application, and no sooner can the pharmaceutical

[291] Gambardella (2006), p.13.
[292] Arai (1999), p.34.
[293] European Commission (2009), p.11.
[294] Cohen (2002), p.1354.
[295] European Commission (2009), p.10.

company initiate the authorisation process which regularly exceeds the date when the patent is granted. But without the authorisation the company cannot exploit its patented drug. Therefore article 13 Supplementary Protection Certificate Regulation extends the term of patent protection to the period which elapsed between the date of filing the patent application and the date of the authorisation for marketing the drug, but no longer than five years in total.

The extended protection is awarded according to article 3 Supplementary Protection Certificate Regulation only if the product enjoys patent protection, if the product is authorized, if the product has not already been subject to a certificate, and if the product has been authorized to be placed on the market as a medicinal product for the first time. The first authorisation in any of the twenty-seven Member States however is not always easy to reconstruct at the patent offices issuing the certificate, in particular when the pharmaceutical company systematically makes misleading representations and conceals for example earlier technical market authorisations. Such misleading has in one case provided an extended patent protection of seven months.[296]

A non-negligible compound behind the misleading intentions is excessive patenting. Filing numerous patent applications relating to the same drug originates a tight patent thicket surrounding a substance. Fosterage of patent thickets is common practice among pharmaceutical companies.[297] Individual drugs are protected by up to 100 product-specific patent families, which can cover up to 1 300 patents granted or still pending across the European Union's Member States. In case of top-selling blockbuster drugs the numbers are even by 140% higher. In a patent thicket evergreening patents flourish. Either the very same substance remains protected by slightly modified patent applications, or by a combination of several different patents, or the interplay of them makes it impossible for a generics producer to enter the market without infringing any of the patents in the thicket.

Litigations attendant the patent thicket can be relieved by pooling one's patents.[298] Companies, wishing some scope of manoeuvre in the thicket, might conclude a cross-license agreement that allows the parties to produce or market each other's products in exchange for stipulated royalties, or they might conclude a reach-through license agreement that allows the parties to use each other's inventions to develop new inventions.[299] However, at least for these mutually beneficial purposes, the companies' licensing practice is to the most bilateral. Four out of five companies requesting a license obtain a license at all.[300] The broader the scope of protection, the more unable or unwilling companies seem to grant licenses to other companies upon mutually agreeable terms.[301] Compulsory licensing as under article 12 Biotech Directive or article 31 TRIPS Agreement of WTO, binding to the European Union and its Member States, is to no avail when the patent holder is exploiting her patent on the common market. On top of that, compulsory licenses are non-exclusive or shared. Shared licenses allow the holder of a patent granting a license to an indefinite number of requesters; whereas exclusive licenses exclude the granting of a license to someone else than the licensee. If at all, most patent holders grant exclusive licenses, because these are worth more to the licensee than shared licenses through providing him an advantage over his competitors on the market. Thus, the number of exclusive licenses outnumbers nine times the number of shared licenses.[302] In

296 COMP/37.507 *Generics/AstraZeneca* (2005), para 681.
297 European Commission (2009), p.10.
298 Overwalle (2009), p.432.
299 Resnik (2001), p.37.
300 European Commission (2009), p.16.
301 Merges (1990), p.885.
302 Oliver (2009), p.9.

general, however, companies show little interest in generating royalty income from licensing.[303]

Sometimes it happens that companies agree to license, or more exactly, to cross-license their patents. Then however they are very likely to pursue other interests, interests that lie outside the realm of a knowledge economy's competition based on innovations. In fact, these interests might well be anti-competitive in nature. When companies cross-license, this might be interpreted as a sign for collusion, because patent pools allow the cross-licensing companies to take collectively full control of a technology area, and thus to install a monopoly.[304] And this monopoly is bound to endure, because new companies, which do not have a patent portfolio to license them in into the patent pool, cannot legally compete with the companies participating in the pool. Patent pools therefore can amount to insuperable barriers to market entry.[305] Monopoly, dominant position and foreclosure are matters of anti-trust authorities. Hence, the European competition law is supposed to counter abuse of European patent law.[306]

Competition law however cannot overrule the chartered right of patent holders to decide exclusively on their licensing strategy. In biotechnology the companies' reluctance to license their patent rights caused economic concern to the extent that the OECD launched in 2006 guidelines for the licensing of genetic innovations. Hence, it is less the patents that blast the market of inventions, but the way companies exploit patents. Patents, it seems, are incrementally used as a parasite of a company's own bygone inventions or of others' inventions, or they are used as tools in strategies of deterrence and harm which are not fostering innovation, least of all enhancing social welfare.[307]

It must be reminded, that the net result of these harmful strategies cannot be judged here because of the lack of a comprehensive economics of innovation with respect to patents. The beneficial effects of patents might nonetheless prevail. Still, most of the patents granted follow the strategic purpose of producing and marketing exclusively an invention. But already one third of the European patents are not used to innovatively improve products or manufacturing processes.[308] About half the patents of this percentage are used for blocking purposes; the other half are sleeping patents. A full fledged economics of innovation will have to take into account the economic costs emanating from the transposition of the harmful patent strategies of companies.

3.2.3 Complements and alternatives to patents

Most of the established effects of patents appear rather detrimental than beneficial to knowledge economy. It is therefore advisable to have a look at alternative tools applied on the market to exploit inventions, and compare their importance for companies with the importance of patents. Such a tool is in the first place secrecy, the primary target of patent law. Because in secrecy a company's knowledge is kept secret, competitors can usually make no use of it in the sense of broadening their knowledge, improving their technological skills, and inventing better technologies or products. It is these detriments of industry secrets to economy and society from which patents derive their legitimacy – together with the public good feature

303 Arai (1999), p.34.
304 Guellec (2007), p.102.
305 Boldrin (2008), p.77.
306 Overwalle (2009), p.432.
307 Beer (2008), p.589.
308 Gambardella (2006), p.ii.

of innovations.[309] However not everybody has the skills to understand the technicalities of an innovation, least of all the capacity to exploit an innovation commercially, even if the underlying knowledge is disclosed. And patent protection might only be an alternative to secrecy, if an innovation cannot be kept secret for twenty years *and* there are no other tools available to exploit an innovation profitably. This however is seldom the case.

Industry secrets have the advantage that they do not require disclosure of know-how, that innovations are protected for the time they are kept secret, while patents lapse after twenty years, and that secrecy spares a company the cost for acquiring and defending a patent.[310] To what extent companies utilize the advantages of secrecy is difficult to assess because there is secrecy over secrecy. Since companies keep it secret whether they rely on secrecy, empirical research of industry secrecy is notoriously unsuccessful.[311]

Empirical research on companies' reliance on other tools for the exploitation of innovations has been more successful. Studies of the aircraft and semiconductor industry have shown that lead time is a major tool for appropriating returns on innovative investments.[312] A first mover in the market can reap prices above marginal cost accruing from her economic monopoly position as long as she is ahead of her competitors with her product design – and as long as a market for that product exists; the increasingly shortened life cycles of products rarely endure twenty years. The first company to launch a product on the market establishes a trademark representing the company's innovativeness, and it establishes a brand for the new product. For these reasons, the first mover is generally able to obtain and maintain higher prices for a product than later entrants to the market. Leading time in the pharmaceutical market provides a company the advantage of brand loyalty and of benefiting from physicians' inert habit in prescribing drugs.[313]

Another advantage accrues an innovative company from the learning curve. Competitive learning curve advantages build on leading time and represent the initial difficulty of learning something new. After the initial lesson is learned, the knowledge gain speeds up quickly and then slows down over time manifesting saturation in the field. The learning curve implies that the more often a task is performed, the less time will be needed to repeat it. Skilled employees work faster and make fewer mistakes. Learning thus reduces a company's cost to produce a product. Hence, an innovator exploiting her invention will produce it more efficiently than her competitors and thus will make higher profits.[314]

A final tool to gain advantages over competitors is marketing: a visible presence of an invention is important in an economy that is driven by demand, and not by supply.[315] The innovative product policy of a company is backed by tailored communication and distribution policies. Advertising, public relations, sales promotion and special services related to an invention establish an invention as unique and aggravate a successful market entry of imitating free-riders. Thus, marketing efforts amount to a considerable protection tool for innovative companies.

---

309 Rosenberg (2004), p.81; Guellec (2007), p.50.
310 Hettinger (1989), p.33.
311 Weil (1989), p.31.
312 Levin (1987), p.784.
313 COMP/37.507 *Generics/AstraZeneca* (2005), para 542.
314 Spence (1981), p.52.
315 Schmookler (1966). p.180.

As a matter of fact, companies generally regard lead time, learning curve advantages, and marketing efforts as substantially more effective than patents in protecting their inventions.[316] For a company to seek patent protection the respective invention needs to show four features. In this sense, a company climbs up a decision tree with four branches: First, the invention must be such that it can be posited it in words, or deposited at a biobank; else the invention is not patentable at all. Second, the invention must be observable when in use and reproducible at low cost; else secrecy is more advantageous. Third, the invention must be of enduring value on the market; else lead time is crucial. Fourth, the invention must be basic or top – depending on the perspective – in the sense of being based on cutting-edge or avant-garde science; else competitors can invent around the invention, making the pursuit of the learning curve or marketing efforts a more attractive source for profits. If an invention unites all these four features, a company would rationally opt for a patent. It would opt for a patent system under a fifth condition: the invention must be independent of other patented inventions; else the company had to hope for a license and pay royalties or was threatened with litigation costs for infringement procedures.[317]

Arguably very few inventions display all five features. Any missing feature diminishes the incentive to file a patent application. The fewer incentives however the patent system offers to companies, the lesser patents are filed for protective purposes expressly, which explained the substantial share of patent applications for blocking purposes. Considering (a) the pursuit of destructive and anti-competitive strategies instead of pro-innovative strategies, what substantiates the observance that patenting is only a weak indicator for innovation, (b) the missing link between patents and innovation, resulting from inconclusive attempts of economic theory to attribute to patents a positive function in knowledge economy, (c) the negative effects of the patent system, resulting from the complexity of patent thickets as a consequence of increased patenting, which invite infringement and validity proceedings in a context of legal uncertainty what finally leads to a distortion of competition; and (d) the reliance of companies on alternative means to exploit their innovations, makes a patent system hardly justifiable. At least, the actual exploitation of patents seriously questions the legitimacy of any patent regime.

3.3 The biotechnology market

It seems so far that industry was better off without a patent regime. The whole industry? No, there shall exist but one exception: biotechnology – and in particular the pharmaceutical industry.[318] The pharmaceutical industry deems patents to be very effective in capturing and protecting competitive advantages of innovative drugs,[319] and therefore heavily utilizes the patent system: about one third of the 360 000 patent applications a year worldwide stem from the pharmaceutical sector.[320] The argument for the industry's need for patents clearly follows the same line as the argument for the extension of the patent life time by means of a supplementary protection certificate: as it takes ten to twelve years to have a drug marketed after the patent was filed, the drug generates revenue to the company only for eight to ten years. An economic monopoly on a new drug is needed to generate extra profits for extra costs. These extra costs stem mainly from investments in research and development of new drugs, and

316 Levin (1987), p.795.
317 Winter (1989), p.50.
318 Lessig (2004), p.258.
319 Winter (1989), p.47.
320 Beer (2008), p.21.

subsequent clinical trials to obtain the authorisation from health administrations to market the drugs.[321]

So the argument goes, and we will have to see whether the pharmaceutical industry lives up to it. The biotechnology industry now not only lays the foundation of modern research in the pharmaceutical industry,[322] but is also said to depend existentially on patents: without patents the biotechnology industry – not to be confused with industrial biotechnology – could not have come into existence for four reasons.[323] First, the expansion of patents into biotechnology created property rights in things that were previously outside of the realm of what could be owned. Second, patents provide evidence to venture capitalists for future commercial exploitations which are worth present investments. Third, patents give assurance to investors against endless legal wrangling, if commercially exploitable inventions pop up. Fourth, patents order the complex innovation process in which disparate interests are interlinked, interests of patients, farmers, academic and commercial researchers, test persons, universities, start-up firms, government, and industry.

The first reason can be ruled out immediately. Though the Biotech Directive expands the scope of patentability and protection, it does not constitute property rights. No patent regime does. A patent holder does not own anything but the patent document. The patent confers to her the right to exclude others' commercial exploitation of the patented invention. It includes, that others take possession of the patent publication, that they learn from it, rebuild the invention for experimental purposes, or that they purchase the invention on the market thereby creating ownership rights in it. Hence biotechnological inventions or biological material has not become more inside the realm of what can be owned than previously. The argument of a new class of property in biotechnology, however important property is for economy, entails an unforgivable confusion of the concept of a patent in patent law.

3.3.1 Network economics in the sector of biotechnology

The biotechnology industry indeed is special in certain regards, and it has to be analyzed how the specialties influence innovation and investment in innovation in this sector of economy. The most distinctive characteristics of biotechnology industry compared to other industries are its recency and its knowledge-intensity and -sensitivity. Taking off in the late 1970s biotechnology industry still is in its early stage, where competitive cooperation and dissemination of knowledge between companies is crucial for innovation. The image of biotechnology industry is dominated by small and middle sized enterprises which entertain manifold relationships with universities or other firms, most particularly with large pharmaceutical companies:[324] as of 2004 already more than half of the research projects carried out in the pharmaceutical industry had some biotechnological foundation.[325]

Though some biotech dedicated firms merge with pharmaceutical companies, more new start-ups enter the market with the purpose of commercializing biotechnological research results. These dynamics led in the highly competitive environment of liberal markets to the formation of a continuously evolving, complex network.[326] The design of this network is shaped by the

[321] Guellec (2007), p.125.
[322] Boldrin (2008), p.222.
[323] Jasanoff (2005), p.204.
[324] Oliver (2009), p.29.
[325] Boldrin (2008), p.222.
[326] Oliver (2009), p.2.

life cycle of biotechnological products. In the pioneering phase, where knowledge is the limiting factor, the network connections function as transmitters of the knowledge needed to advance the efforts towards a marketable good. Commercial researchers participate in scientific congresses, and cooperate with academic researchers from universities, or with commercial researchers from third firms. The researchers learn from each other. This learning network changes when the exploitation phase is reached. Then all the previously absorbed knowledge needs to be captured within the firm and the institutional boundaries are redefined; then the product is being developed internally. The transition from cooperation to competition remains competitive: the competition on innovations enabling a product becomes a competition on innovations specifying a product. Hence, in the exploitation phase of the generated knowledge the biotech dedicated companies compete for being the first to place a product on the market, and they compete for the product specificity or applications, but they do not compete for the product in itself.[327]

The networks economics of biotechnology is characterized by a common knowledge-base on which biotechnological products with all their specificities and applications are built. Knowledge of how to sequence genes and determine their function can be applied in primary production of genes, but also in health biotechnology to raise tissues for implantation purposes, in agricultural biotechnology to engineer drought tolerable plants, or in industrial biotechnology to grow high-energy biofuels. Because of the multiple applicability of the knowledge resulting from cooperative research, the benefits of it are magnified when the knowledge gained for one application spills over to other fields of biotechnology and is absorbed by researchers working on different applications.[328]

The spillover effects are not restricted to biotechnology industry. Firms in general focus increasingly on knowledge generated outside their own region; they absorb it either from the public domain or, more importantly, from other private firms, independent of their geographic location.[329] It turns out that productivity growth of a company is more sensitive to research spillovers than to the own knowledge stock of research created by the company. And the spillover effects increase with the amount of own research and development, because with its own research a company acquires the absorptive capacity to absorb external knowledge.[330] Besides, intramural expertise gained through researching on its own, means for a company the entry ticket to learning networks of a competitive knowledge economy.[331]

Apart from the common knowledge-base, biotechnology industry is economically characterized by key figures such as number of firms, research and development expenditure, venture capital, employment, sales, and number of patents.[332] Most of the biotech dedicated firms are located in the United States and the European Union. On both markets the survival rate of the companies is low with a stable three and a half years average half-life.[333] The mainly small and medium sized enterprises employ 96 500 people in Europe.[334] Almost half of them are involved in research and development functions, what is hardly surprising, because biotechnology industry is highly knowledge-intensive. With respect to these figures, as well as with regard to patenting, the European Union is on a level with the United States or even out-

[327] Oliver (2009), p.200.
[328] OECD (2009), p.268.
[329] Gambardella (2006), p.30.
[330] Mohnen (2009), p.126.
[331] Oliver (2009), p.191.
[332] OECD (2009), p.4.
[333] Bains (2009), p.43.
[334] COM (2007) 175, p.4.

performs it. However with respect to venture capital and sales, European firms fall years behind.[335]

A look at the products invented and marketed is revealing and indicates a considerable innovation gap between the European and the American biotech industry. While Genentech, Alcon Labs, Amgen, Myriad, Genzyme or Eli Lilly and the like launched in the United States cutting-edge products of its time such as recombinant insulin, growth hormone, interferon, interleukin-2 and erythropoietin, which generated a fortune in sales because of their ground-breaking innovativeness, their European pendants like Serono, Celltech, Vernalis, Inno-genetics or Morphosys invented around erythropoietin, launched some diagnostic reagents and came up with variants of well-known substances, so-called me-too drugs.[336]

These products may be the basis of good business, but they do not represent avant-garde science which attracts lots of investment, at least lots of venture capital. Thus, it seems that it is the level of innovativeness, the length of the inventive step so to say, that stimulates further investments in further innovative efforts. Investment in me-too drugs leads only by chance to important inventions, although it may lead to good return in investment. Indeed, it is a common strategy of pharmaceutical companies to develop drugs that are very similar to but not the same as patented drugs. This allows competitors to acquire a small market share of a blockbuster drug without paying royalties to the patent holder.[337]

Anyhow, no patent holding company would license the production and marketing of a block-buster drug. On the contrary, the company often tries using any trick to prolong the lifetime of a blockbuster's patent, in order to exploit it exclusively as long as possible. The prolongation forecloses the market entry of generics producers that produce and market a drug whose patent protection has expired. Generic drugs occupy more than half of the drug market in Europe;[338] and generic drugs save the health system on average almost twenty percent of its respective costs one year after they became available for the first time.[339] That explains why any prolongation of a drug's patent protection obtained by fraud causes considerable damage to social welfare.

With regard now to the budget of the top thirty pharmaceutical companies it emerges that 70 to 75 percent of the research and development expenditures go towards me-too drugs, and only 25 to 30 percent of it are invested in inventing new drugs, including the costs of failed research projects.[340] On top of that, research and development is only a minor item on the balance sheet compared to the marketing cost. Pharmaceutical companies spend about twice as much on promotion and advertising as they do on research and development.[341] In this regard pharmaceutical companies act principally in the same manner as companies in other industries. They exploit lead time and generate revenues through branding and direct market-ing vis-à-vis physicians and clinicians. Innovative research and development has only a comparably small share in a pharmaceutical company's budget. The cost for innovative research is at least low enough not to boast it as an extra cost that alone legitimated privileging a pharmaceutical company over a generics producer with patent rights to recoup its expenditure, because both have to incur the main costs, which are the costs for clinical

335 Bains (2009), p.17.
336 Bains (2009), p.18.
337 Resnik (2001), p.41.
338 Boldrin (2008), p.213.
339 European Commission (2009), p.9.
340 Boldrin (2008), p.236.
341 Boldrin (2008), p.226.

trials required for the authorisation to market a drug. Therefore, the pharmaceutical industry does not live up to the argument of extra profits for extra costs. This leaves us with only just three reasons that specifically justified patents in the area of biotechnology.

3.3.2 Economic role of patents on biotechnological products

About five percent of all patent applications filed at the European Patent Office concern biotechnological inventions;[342] a share that does not represent the presumed importance of patents for this sector. Admittedly, patents are less important for industrial biotechnology than for health biotechnology, and the actual and potential market share of industrial biotechnology exceeds that of health biotechnology.[343] Thus, the explanation for the comparably low percentage of biotech patents is that a large part of biotechnology is not in need of patents and does in fact not patent, because companies in the field of industrial biotechnology frequently rely on secrecy.[344] Biotechnological process engineering and the opitimization of enzymes for customised production processes require special skills which are either not yet verbalizable, so-called tacit knowledge,[345] or not observable, at least not to an extent that subjected the invention to reverse engineering. Therefore, secrecy is preferable to patent protection in industrial biotechnology.

This explanation however is incomprehensive. The patent system on its own lends itself to an argument for secrecy. Because only the first person who files a patent application is entitled to patent protection according to article 60(2) EPC, any research being done on a product which might qualify for a patent but is not yet sufficiently developed to be filed at the European Patent Office, must be done in secrecy in order to avoid that the patent may be granted to a competitor, even if the competitor was not the first who finally invented the product.[346] Thus, an initial effect of the patent system on the network economy of biotechnology is the provision of an incentive to enhance secrecy instead of publicity. This must be considered detrimental to an industry that bears on a common knowledge-base.

Nevertheless, the argument goes that patents are vital for the economic network of the biotech industry, because they ensured the existence of the many small and medium sized enterprises constituting the network. Many of these companies have been unable to raise venture capital or other investments unless they could demonstrate that they already had or were able to develop a patent portfolio, in particular with regard to DNA technologies.[347] Still, patents are no reliable evidence for future market success. Patents differ. The share of the European Union in biotechnology patents filed at the European Patent office between 2002 and 2004 was 34,8%, as compared to 41,1% for the United States.[348] Although biotech dedicated companies located in Europe file almost as many patent applications as their American counterparts, they attract disproportionately less venture capital.[349] Presumably, the innovative potential of a product and the innovative performance of a company weigh heavier in investment decisions than patent portfolios. It is the innovation that sustains a start-up, rather than the patent on it.

[342] Beuzekom (2006), p.44.
[343] OECD (2009), p.16 and 19.
[344] OECD (2009), p.153.
[345] Polanyi (1958), p.27; Nonaka (1998), p.24; Mirowski (2004), p.58.
[346] Oliver (2009), p.125.
[347] Doll (1998), p.690; Oliver (2009), p.127.
[348] COM (2007) 175, p.4.
[349] Nenow (2001), p.572; Bains (2009), p.58.

Quite contrary to the argument, the patent system is likely to erode the existence of small biotech dedicated firms. Because most of the patents – whether exploited or not – are held by large multinational companies with a dominant position on the market, only very few start-ups can really compete with them, unless they find a niche in the market where they can establish their business. The fostered patent thicket is too high a disincentive for market entrants to compete with the dominant patent holders. Not having the financial backbone to fight through potential litigations, the small biotech companies either cooperate with the multinationals or they try to find something they can offer them: a patent for example. Thus, the patent system forces many small biotech dedicated firms to set themselves up as one-invention companies, aiming only at being purchased at the highest possible price by a multinational company, mostly a pharmaceutical one.[350]

As patents do not strictly attract investment in research and development of biotechnological products, they do not strictly stimulate innovation either. Only the antipsychotic chlorpromazine and the contraception pill out of the fifteen most important medical inventions have been patented, or have been made during a research project set up to obtain a patent.[351] Although innovative does not necessarily mean profitable, the pill is. And so are for example Viagra and Prozac for which a patent has been granted. However, more than half of the top-selling drugs worldwide, such as Aspirin, insulin, penicillin, quinine, or Ritalin, do not owe their invention to pharmaceutical patents.[352] Hence, neither a direct link between patents and innovation nor an indirect link between patents and innovation via investments in innovation can be confirmed for health biotechnology; whereby industrial biotechnology had been declared no principle customer of patents from the outset.

Besides, the notorious exclusivity of patent rights does not play an incumbent role in biotechnology, neither in respect of licensing nor in respect of exploiting. To begin with licensing, two of the most seminal biotechnological inventions were made outside the realm of patents: monoclonal antibodies and recombinant DNA. The technology of monoclonal antibodies alone is used worldwide by 730 firms to detect and purify specific substances.[353] The subsequent downstream patenting by the firms using the two technologies demonstrates that exclusive licenses were certainly not necessary to give companies an incentive to invest in the commercialization of monoclonal antibodies and recombinant DNA;[354] what obviously contradicts the prevalent doctrine of a licence's economic value.

Apart from that there seems to be, at least sometimes, no interest in legal positions that allow for exclusive exploitation of an invention in biotechnology industry. As with DNA sequences, large pharmaceutical companies founded in 2000 the single-nucleotide polymorphism consortium, which isolated and identified the gene sequences and put them on databases accessible on the internet, in order to make it hard for biotech companies to patent any polymorphism because the published sequences must be considered as prior art. This behaviour might be interpreted as the pursuit of a foreclosure strategy to keep potential competitors out of the market; in any case it runs counter to the prevalent narrative of patent advocates that companies benefit from seeking patent protection instead of putting an invention in the public domain. A remarkable interpretation of the anti-patenting behaviour of pharmaceutical companies holds the patent system responsible for the enrichment of the public domain: if the

[350] Boldrin (2008), p.75.
[351] Boldrin (2008), p.229.
[352] Boldrin (2008); p.230.
[353] Oliver (2009), p.130.
[354] Oliver (2009), p.139.

heavily patenting biotech companies had not existed, the pharmaceutical companies would have worked on single-nucleotide polymorphisms in secrecy.[355] Then, indeed, patents had the indirect effect of accelerating research and of enriching the public domain. Patents then had a pressure function: innovate and publish, else others might exclude you from exploiting an innovation.

Economic developments like this may have contributed to the situation that the patent rush in biotechnology between 1991 and 2001 with a growth-rate of 8,3% in Europe per year[356] has slowed down more recently. As a matter of fact patent applications on biotechnological products decreased between 2000 and 2006 by 4,6% worldwide.[357] One explanation of the decrease might be that the criteria for granting patents have become more stringent in biotechnology.[358] The stringency however draws on codifications like the Biotech Directive which come along with an expansion of the scope of patentability; from a broadened scope of patentability one should however expect an increase of patent applications rather than a decrease. A more likely explanation for the decrease is therefore, that companies begin to realize the detrimental effects of patents, such as the permanent threat of enormously costly litigations. A detriment that weighs even heavier when one takes into account that the rate of validity procedures before the European Patent Office is consistently higher for the pharmaceutical sector than for other industry sectors. It is about 8%, whereas the overall average lies at about 5%.[359]

Validity procedures at the EPO take some time. On average it takes more than two years for approximately 80% of final decisions. During this time the patent situation remains unclear and any market progress related to the product is blocked. Any anticipating action only provokes subsequent infringement procedures due to the established patent thicket. In sum, therefore, both the argument that patents procure legal certainty for marketable products, and the argument that patents show evidence for profitable investments are not well-founded. That leaves us with only one rationale for a patent system: the ordering of dissenting claims of different stakeholders in relation to innovation. This rationale provides no economic justification and leads over to the effects on a particular stakeholder: scientists.

355 Guellec (2007), p.125.
356 Beuzekom (2006), p.44.
357 Beuzekom (2009), p.70.
358 Beuzekom (2009), p.70.
359 European Commission (2009), p.12.

4 Dissemination of knowledge

Scientists from public institutions like universities are in charge to generate and disseminate knowledge of public interest, whereas scientists from private institutions like biotech dedicated firms are in commission to generate and appropriate knowledge in order to offer knowledge products on the market where private interests are served. The knowledge disseminated through companies thus reaches in principle fewer people, whereas the knowledge disseminated through universities should in principle reach all people; at least academic knowledge products should spread wider than commercial knowledge products. This however is not warranted due to the inherent incentive in science to pioneer and dominate a field of research, to which end discoveries are camouflaged or kept secret. Thus, patents could have a disseminative effect on science insofar patents' incentive patterns beat the ones of science and ensured earlier publication.

The final chapter thus considers the effects of patents on the dissemination of knowledge as envisaged by the European Union's knowledge policy. As a proxy for indicators of knowledge dissemination will be taken the scientists' publication activity, licensing activity, and sharing of biological material activity. The publication activity comprises patent publications and publications in scientific journals. An analysis of these activities will show that – against the expectation based on the assumed tasks of scientists above – academic scientists patent as heavily as commercial scientists publish in journals. This indicates a convergence of the scientists' disseminative activities. Indeed, it is only the non-exclusive licensing practiced by most universities that differs significantly from the activities of their corporate counterparts: Biotech companies regard biological material as their private property that is pocketed exclusively even when they publish research results on the material's characteristics.

The convergent activities will be developed into a coalescence of science, technology and industry with ever more strengthened links between them. The linkage of science and industry will be presented as learning network within knowledge economy, in particular with regard to biotechnology but with a highly visible trend transferable to other industries. This trend in turn will be connected to the industrialization of science which involves that activities within science are constrained by private law rather than by rules of a self-governed institution. The resulting contractual knowledge exchange not only between companies, but also between companies and universities, and between universities themselves reveals the competitive milieu of knowledge economy in which science has arrived.

The developed inextricable networks of knowledge contributors and exploiters in knowledge economy predict academic and commercial scientists to be competitors on the market – who rely intermittently on phases of intense cooperation. It will be seen that universities actually display competitive market behaviour: In order to draw profits from their knowledge they actively hunt up and sue third parties who are allegedly exploiting one of their many patented inventions, and thus turn knowledge products artificially into a scarce resource. This competitive market behaviour questions the privilege of academic scientists to make use of patented inventions for experimental purposes. Deprived of the research exemption, I will argue, scientific progress will be impeded and slowed down. As a consequence the dissemination of knowledge is delayed because scientific discoveries are made later on, if at all.

4.1 Knowledge productivity of science

Science is supposed to be the primordial source for the creation of knowledge. Sharing of positions, arguments, or materials is deemed to be a matter of course in science. It turned out however, that scientists publish their findings not only to promote knowledge, but also to promote their position within the hierarchical order of science. In the fierce race for scientific breakthroughs, recognition and reputation go with the first who announces them, and not necessarily with the ones who test and confirm them. This leads to the backfiring effect, that smaller findings, creative approaches, or substantial arguments are held back to retain the chance of coming up first with the big discovery. Then, the dissemination of knowledge has to retreat in favour of scientists' private interests which delay scientific progress. It remains to be seen whether patents aggravate or even relieve this situation in science.

4.1.1 Common indicators for scientific and technological knowledge dissemination

To measure how far knowledge has disseminated is as complicated as measuring the degree of innovation within economy. Thus, respective measurement results remain controversial even in clearly circumscribed, locally restricted research fields such as schools, where the knowledge dissemination is regularly measured in student assessments to evaluate the skills of pupils in a worldwide comparison. When not only the tuition of teachers is the source of knowledge but all sorts of publications, and when not only pupils are the recipients but society at large, the vagueness of measuring the dissemination of knowledge becomes apparent. Therefore, indicators like the stage of development of an industry, regulatory acceptance of a technology, number of business partners, journal publications, citations, patents or distribution licenses are pretty broad.[360]

These indicators standing on their own cannot tell much about the dissemination of knowledge, because too many variables are involved in their determination: some industries are not knowledge driven whereas others, where knowledge abounds, do not get off the ground; some technologies might not be accepted for political reasons; business partners may divide the labour; not all journal articles are equally important; scientists establish cartels of mutual citation;[361] patents, too, differ; and the distribution of licenses depends on the willingness of patent holders to license; and more. The indicators gain importance in time series analyses which demonstrate changes of the relevant fields. These changes would be more meaningful in respect of knowledge dissemination than isolated key figures because they represented the dynamics of knowledge's public life more adequately.

Indeed, the knowledge dissemination might already stop at the border of science. For the knowledge based link between science and technology is considered to be problematic. Thus, science might not be a part of the value added chain of innovation. New technologies seem to flow from old technologies rather than from any interaction between science and technology.[362] Many technologies are only partially understood scientifically, and medical scientists know only for very few drugs why they are effective. Science and technology seem to go separate ways. Even in knowledge-based fields, technologies advance in an evolutionary

[360] Carlsson (2000), p.25.
[361] Galjaard (1999), p.75.
[362] Solla Price (1965), p.561; Gibbons (1974), p.231.

process.[363] Thus, there would be no dissemination of knowledge between academia and industry, and indicators could focus on each area separately.

On the other hand, almost all valuable discoveries in biotechnology were made by scientists who were looking for something else entirely.[364] Significant advances of knowledge often result from basic research, not from applied research. Applied research only occasionally yields much needed breakthroughs for the development of a desirable invention. This has an economic reason: It lies in the nature of breakthroughs that direct research efforts to achieve them are unpredictable and therewith the costs involved extremely high.[365] Hence, the research is not even attempted. Those in task of developing long-range communication means, did not research into electromagnetic waves, nor did those in task of developing bombs for mass destruction research into nuclear fission. In terms of biotechnology, those trying to understand how life works would thus be more likely to contribute to the development of effective drugs.

However great the utility of scientific breakthroughs for industry might be, however strong the influence of science on technology, both share in any case one major feature: universality. A device manufactured at Stuttgart should still work in Rotterdam. Technological inventions are reproducible and controllable just like scientific experiments. This does not imply that any technology transfer between states will result in a successful implementation of that technology in the economy of the receiving state. The success is linked to the geographical distance and respective investments through trade,[366] *and* the ability to decode the information incorporated in the technology.[367] Technology transfer requires knowledge, the capacity to use a tool or run a machine; the training of such skills certainly cannot be reduced to a mere communication problem confined to information channels and coding routines.

The commonality of technical devices and scientific experiments results from the application of methods to generate knowledge. There is a methodological link between science and technology. Hence, one cannot say that both are separate, but still the knowledge transfer between them might vary from field to field and from case to case. As science's contribution to technological innovations remains controversial, it is undisputed that technologies contribute to the progress of science. Little science became big science.[368]

Industrialization finally took science, too. Public research institutes have developed into small and medium sized enterprises with a strict business organisation. The European Molecular Biology Laboratory at Heidelberg has an annual budget of 158 million euros; still three times less than the European Organization of Nuclear Research at Geneva which spent alone for the construction of the Large Hadron Collider 3 billion euros. Big science needs big money, each year more. This does not mean that science became the handmaiden of business,[369] but they grew together, and will grow together in a knowledge economy. On the market, science found in venture capital a new money source which was and still is ready to invest in start-up companies built on scientific discoveries. And once capital was attracted, obstacles to patentability incrementally dropped away.[370]

[363] Nelson (2006), p.907.
[364] Bains (2009), p.190.
[365] Nelson (1959), p.301.
[366] Tinbergen (1962), p.263.
[367] Arrow (1969), p.33.
[368] Solla Price (1963), p.7.
[369] Buttel (1989), p.131.
[370] Merges (1996), p.157.

4.1.2 Patenting in science

The commercial alliance with venture capital implied the maxim to sell as much as possible of the scientific stock, including basic discoveries like gene sequences. Gene sequences qualify particularly for business based on patents, because there is no way to invent around: they are basic.[371] And they are describable in technical terms, they are enduring (operating now for 3,8 billion years), and they are observable at least indirectly through X-ray crystallography. Thus, a gene sequence fulfils all four criteria of the patent decision tree, to decide whether to let patent an invention. However, gene sequences are not independent; in order to work they are dependent on proteins or other genes. And this dependence makes their industrial application susceptible for lavish licensing or inadvertent infringements and extremely expensive litigations, since some biological compounds of different gene-based inventions quite likely overlap in their utilization.

Basic research has become exploitable. Pharmaceutical companies no longer base their drug development on trial and error, but develop drugs along scientific knowledge of genes, proteins, and associated biochemical pathways in organisms.[372] Basicness is no hindrance to exploitation. Therefore, basic inventions threaten even more the market position of competitors; this is because patents on basic inventions, even if not immediately marketable, shield a whole variety of products on future markets. At any rate, that European patents from universities are opposed less frequently than patents from companies does not imply that the academic patents are more basic.[373] It is more likely that most of the academic patents are not worth an opposition. And that is because patents have become a career asset at industrialized universities.

Sure, academic researchers from universities have yielded major scientific results without the incentive of patents, and they continue to do so.[374] The concentration of all the fame and reputation on the first scientist who comes up with the result remains the central incentive for scientists to innovate, and keeps the routinized competition among scientists in place. The patent system adds on only one more incentive: the incentive to patent. Apart from distinguished titles and lengthy publication lists, patents are welcome insignia to stratify the hierarchical order of scientific reputation. And they attract third-party funds. Additional revenues however are generated by patents only for very few universities.[375]

The industrial metamorphosis of universities is well represented in patent statistics. Patent applications from universities increase dramatically, in particular in biotechnology. And the sheer number does not fully represent the actual inventions made at universities, because the majority of academic inventions are filed by individuals or companies, and not by universities.[376] Nevertheless, the counted patents from universities between 1980 and 2004 have multiplied four-fold in the United States,[377] and even seven-fold in Europe.[378] The number amounts to a 3,5% share of the overall applications at the European Patent Office. University patenting is extremely intense in the sector of biotechnology. About half of the academic patents are

[371] Matthijs (2004), p.1359; Rosenberg (2004), p.92.
[372] Rai (2003), p.289.
[373] Czarnitzki (2009), p.4.
[374] Goldman (1989), p.76.
[375] Washburn (2005), p.153.
[376] Guellec (2007), p.185.
[377] Gurry (2007), p.256.
[378] Guellec (2007), p.188.

meanwhile based on biotechnology inventions,[379] such that one out of five patents on biotechnological products or processes is held by a university.[380] This is highly remarkable compared to the much lower overall share of universities in patent applications, and thus shows the high status of biotechnological patents at universities. Indeed, until 2003 the top holder of biotechnological patents in the United States was the University of California at Los Angeles.[381]

The tremendous patent output of universities implies potential impact on research, particularly in the biotech industry. When the academic research sector has become a major contributor to the pool of biotechnological patents, one should assume that the commons of knowledge suffered and the public domain ran dry. This detriment would be indicated by reduced publicity, by a creeping extinction of knowledge's public life, or, more profane, by a decline in publication. This is not the case. On the contrary, ever more journals dedicated to biotech related topics are being issued,[382] and publication on the matter proliferates. The profile of the agents on the public stage however is quite surprising; the commercialization of basic science seems to reverse the image of science and industry: academic researchers patent and commercial researchers publish.

Commercial researchers publish mainly in order to enhance the absorptive capacity of their company which facilitates the incorporation of knowledge created elsewhere. Published papers are for companies the entry ticket into the learning network where they have access to cutting-edge science, just as university spin-offs seek entrance with patents to access venture capital. In this network participants have to offer knowledge, in order to get knowledge or money for further research in exchange. A solid journal portfolio of a company thus displays to network participants a strong knowledge capacity that invites for intensive and mutually beneficial cooperation. Therefore, commercial researchers publish – and in the end not less than their colleagues from public institutions. Companies like Sandoz, Sanofi Aventis, Ciba, Roche, Philips, Siemens, Hitachi, and Toshiba publish as many papers as medium-sized universities.[383] On the other hand, prolific authors from universities document superior patenting activity. Statistically, a high rate of publication is significantly correlated with an increased probability of filing a patent. In this respect, at least, patents do not seem to decrease the productivity of scientists.[384]

Like patents, publications differ in quality and thus in their importance for society. A common indicator for scientific performance and the degree of dissemination of published knowledge is the frequency of a publication's citation. The more often a paper is cited, the more it seems to be distributed, and the more important it is deemed to be. This line of reasoning urges the assessment that publications from private researchers are most important: The average citations per paper of AT&T, Genentech, or Telcordia Technologies exceed that of top ranked universities.[385] In return, the fertility of university patents in terms of downstream inventions, on drugs or chemicals at least, is deemed to be higher than the ones from pharmaceutical

379 Owen-Smith (2003), p.1695.
380 OECD (2009), p.267.
381 Gurry (2007), p.256.
382 European Commission (2006), p.31.
383 Hicks (1998), p.403.
384 Guellec (2007), p.188.
385 Hicks (1998), p.403.

companies.[386] Overall, the importance of university patents has declined, and the mass of academic low-quality patents obliterated any differences to corporate patents.[387]

Surprisingly, high-impact publications stem from commercial researchers, whereas high-impact patents stem from academic researchers. This turns the classical scheme upside down, that corporate patenting exclusively serves private appropriation, while academic publishing advances the public dissemination of knowledge. Note that journal publications cannot be equated with dissemination of knowledge in public, rather with the commons of knowledge; that is, journal publications amount to knowledge products, and not automatically to knowledge. Since in order to induce knowledge, i.e. skills, the publication must be at least sufficiently clear to make the described experiments reproducible. However, the techniques revealed in the methodology section of published papers are often presented insufficiently, because scientists try to protect their competitive advantage through secrecy. Patent applicants, however poor their disclosure has become, must be more disciplined; without sufficient revelation of the techniques they run the risk of getting the patent invalidated.[388]

4.1.3 Licensing in science

Patents may not only indicate quality of an invention, they also may ensure the quality of its dissemination.[389] Poor and faulty copies of an invention might be impeded with the help of patent rights by licensing the use of an invention to manufacturers who exhibit high quality proficiencies. In case of a useful liver extract, which was not patented, its standardisation failed and quality control of the product was hard, because the academic inventors lacked the authority to confer the production of the extract exclusively to qualified companies who had guaranteed a product free from impurities. With a patent on the extract the university would have been able to do so.[390]

Not putting academic inventions in the public domain at no cost to companies and patenting them instead thus may be justified by quality concerns. The economic justification that companies will be unwilling to invest in developing an invention to the marketable stage without exclusive licences, which prevent competitors from developing the same invention,[391] has been ruled out by the example of monoclonal antibodies and recombinant DNA which attracted tremendous investments without being patented. Scientific cutting-edge inventions provide an incentive for investments in innovation, even though they are freely available or licensed to many competing companies. Therefore, the fact that academic patentees assert far less than full exclusionary rights,[392] so that over half of university licenses are non-exclusive (with some patents licensed to hundreds of companies),[393] does fairly contribute to the dissemination of academic inventions without hampering competition in knowledge economy.

A putative reason for the non-exclusive licensing practice of universities lies in the fact that more than half of the licensed patents represent research tools.[394] These tools' primary use is

386 Mohnen (2009), p.125.
387 Henderson (2002), p.238 and p.256.
388 Hicks (1998), p.408.
389 Lemley (2004), p.132.
390 Weiner (1989), p.95.
391 OECD (2009), p.267.
392 Merges (1996), p.150.
393 AUTM (2006), p.42.
394 Rai (2003), p.292.

to advance scientific research, rather than to reach the stage of marketability. By allowing for a wide application of these tools, universities cultivate their fields of research. The more people work on it, the more sustainable academic research can be upheld; in particular, when one considers the publication activity of private researchers from companies. In this sense, non-exclusive licensing is almost existential for universities in providing them a broader social legitimacy. Exclusive licensing narrows future research activities to fewer players, most of them academic scientists, and therewith hazards the danger of drying out the whole field.

In sum, major scientific results in biotechnology achieved by universities, like the discovery of a gene or the identification of an active site of a protein, are published quickly for reputation's sake – and they were no major results if they were not reproducible. The intermediate steps to major results tell a different story: in publications of minor results scientists are eager not to disclose too much in order to preserve their competitive advantage. Of more concern than cryptic publications, finally nine out of ten publications remain unperceived, however is the exchange of biological material. Cell lines or tissues are handled with idiosyncratic care, to make sure that nothing of a university's biocapital can be stolen or embezzled, including its interest. Biocapital got a high market value, such that biomedical researchers already began to object to the prices they shall pay for genetically engineered cell lines or organisms.[395]

Hence, it is the competitive routine of scientists that hinders the dissemination of scientific findings, rather than patents or patenting. This has become most obvious in the scientists' reluctance to share biological material; the reason for the reluctance being that sharing access to unique material not only enabled peer scientists to replicate the results, but also allowed them to compete more effectively with its possessor in making new discoveries.[396] This directs the line of view to supplementary and complementary mechanisms that guide the behaviour of scientists, encouraging the development of knowledge markets and sustaining the freedom of research in the public sector.[397] The first mechanisms in sight are contractual in nature.

4.2 Industrialized science and commercialized knowledge

Supplementary mechanisms that determine scientists' behaviour are either due to the network economy of biotechnology or must abide to it. Biotechnology's network economy gains added value from inter-organisational cooperation and thus crucially depends on cooperative elements notwithstanding competition. The dependence finds a suitable expression in the common knowledge-base. The knowledge needed for the commercialization of a specific biotechnological product is scattered within the boundaries of various institutions; among them most importantly universities: the success of new biotech companies depends critically on scientific innovations from cooperating universities.[398] Thus, in health biotechnology universities, hospitals, and pharmaceutical companies interact closely in the development of new drugs.[399]

[395] Resnik (2001), p.53.
[396] Eisenberg (1987), p.197.
[397] OECD (2009), p.152.
[398] Oliver (2009), p.20.
[399] Metcalfe (2007), p.486.

4.2.1 The rise of contractual agreements in science

But doing business with research results from universities is also risky business.[400] Not all scientific inventions are industrially applicable, not all academic patents are fertile. The risk consists in not knowing beforehand which inventions are worth commercial exploitation. Yet, universities are in Europe under growing pressure to translate their research results into commercially exploitable knowledge products.[401] Recent success on the market and the predicted increasing importance of scientific results gave universities the self-confidence of stockholders who hold a considerable share in the knowledge economy. Biological material is placed in a treasury chest next to gold and jewellery; and the disposition of a cell line for some experiments is like disposing a 20-carat diamond for glass cutting.[402]

Both the disposing universities and investing companies face individual risks of losing in stock – either in biological or in financial capital – and therefore try to hedge the risks. A common form of risk hedging has become contracts. Universities conclude agreements with biotech companies and other universities when cooperation comes to the transfer of biological material or to the access to biobanks or databases on genes and proteins. These contractual agreements usually prohibit any further distribution of the material or data to third persons, sometimes even stipulate that everything derived from the disposed material further belongs to the disposing university,[403] but more often regulate the patent rights and licensing conditions for inventions made in the course of using the research tools.[404] And the agreements arrange the publication procedure: In case of joint publications usually a time tag is agreed that enables companies to finalize the results in marketable products;[405] and in case of unilateral publications the company is allowed to review the manuscripts before they are published.[406] The contract terms, the involved administrative burden and managerial control of research are by scientists increasingly experienced as handicap.[407] Besides, they are regularly excluded from most of the revenues. Although patents are the result of ongoing scientific cooperation, biotech companies do not share them with universities or other companies.[408]

Thus, the growing marketability of scientific results, their demand from economy and society and their supply by scientists, has introduced new codes of conduct into science. These codes imply a shift from the communist norm[409] of unconditional public sharing of research material to the legal norms incorporated in private sharing of research material under contractual conditions. The exchange of gene sequences, laboratory animals, reagents, data specifications, or background information on published papers, which was once subject to a normative expectation of free sharing, is now subject to material transfer agreements, license agreements, and database access agreements.[410]

400 Sellenthin (2004), p.90.
401 Henderson (2002), p.237.
402 Boonin (1989), p.263.
403 Lemin (1989), p.196.
404 Rai (1999), p.111.
405 Oliver (2009), p.75.
406 Oliver (2009), p.13.
407 Weiner (1989), p.100.
408 Oliver (2009), p.75.
409 Merton (1973), p.273.
410 Rai (2003), p.297.

The erosion of the communist norm further affects the norm of universalism.[411] Without free sharing of research material, confirming experiments become more difficult to be carried out, and the claim to universal validity of scientific research results loses ground. Almost half of the geneticists, who asked at other universities for additional materials or data regarding published research, reported that at least one of their requests had been denied in the three preceding years, what made it impossible for 28% of them to confirm the published research.[412]

The emergence of legal norms regulating conduct in science[413] renders the autonomous codex of science less important. Self-regulation in science does not apply. The conception of science as the whole of institutions and persons autonomously generating and allocating knowledge products in the commons[414] of public life does not fit actual practice in science. Giving and supervising rules, and sanctioning violation of the rules are not self-organized by scientists, but emerge in the interaction with corporate players of the established learning networks that pursue commercial goals. Thus, public science is incrementally governed by private law – and directed by economic interests. Large parts of science have become business; a business that is an integral part of networks of knowledge economy.

4.2.2 Science in networks of knowledge economy

Insofar public science is resituated in a network of private actors, where universities are business partners of biotech companies, the working conditions for scientists change. The network affects science. Science is an integral part of a network that is shaped by academic research and – in a feedback loop – shapes academic research. This network is a learning network in which academic and commercial researchers cooperate in a competitive milieu. The knowledge generated in learning networks means scientific progress and is therefore indispensable for any researcher in the field of biotechnology. That is why an individual university cannot opt to remain detached from the network. Being a full-blown member of the network of knowledge economy affects universities directly and indirectly. Universities must be considered as competitors or as collaborators of competitors; at least with regard to biotech companies. Thus, universities are direct or indirect competitors of biotech companies. And this cannot but imply consequences for scientific research.

Like academic researchers, commercial researchers are reluctant to share biological material or research tools. In a prominent case, commercial researchers refused to deliver a genetically modified organism to the board of editors of a journal, where their paper on the genetic modification should be published.[415] Unlike academic researchers, commercial researchers never adhered to the norm of sharing. Rather, their proprietary claims form the basis of their business. Commercial researchers legitimately pursue commercial interests. Now, in a cooperative and competitive network of public and private institutions commercial interests prevail and guide finally the behaviour of academic researchers, too. Or in ideological terms: the communist norm of public sharing is not enforceable in a capitalist economy based on private property.

411 Merton (1973), p.270.
412 Campbell (2002), p.474.
413 Rai (1999), p.88.
414 Ostrom (2007), p.58.
415 Eisenberg (1987), p.203.

The network of knowledge economy is not only about cooperation, but also about competition. Network participants switch dynamically back and forth between collective cooperation and individual appropriation therewith redefining the knots and edges of the network. When biotech companies have compiled enough knowledge from the network participants to develop intramural a marketable product, they stop to cooperate and sometimes even start to mislead others with regard to a research project; when the product finally is developed and has to be marketed, the companies' actions may even turn aggressive. When Harvard licensed the patent on the onco-mouse to DuPont, the multinational company aggressively marketed the research tool and enforced its patent rights, just like Myriad Genetics did with breast cancer diagnostics based on the patents on BRCA1 and BRCA2.[416]

The recurrent alternation of collective cooperation and individual appropriation follows a spiral pattern of linkages between academic and commercial spheres which emerge at various stages of the innovation process.[417] In such a switching and ever changing surrounding, universities enter troubled waters. They can no longer retreat to the sole role of a non-profit collaborator; within a network populated by companies, a collaborator is almost always the collaborator of a competitor. Thus, the network situation might deprive universities of the benefits from collaborations. Because of patent rights and material transfer agreements a biotech company is not free to share its material and tools with collaborating universities. Patent and contract law restrict the collaboration. Roche, for example, sued Promega, accusing the biotech company of patent infringement, because it had supplied academic researchers with a key component that allowed them to use Roche's patented polymerase chain reaction.[418]

Litigation is an inseparable consequence of patents. And universities must be aware of litigations while operating in the networks of knowledge economy, although infringement procedures against universities still are highly unusual.[419] Companies till now tolerate infringements of their patents by academic scientists for several reasons. Most importantly, companies consider the financial gains from litigation against a university not worth the legal fees, they fear the risk of their patent being narrowed or invalidated during the procedure, and they want to avoid bad publicity when suing a public institution.[420]

To date, universities do not suffer the detrimental litigation effects of the patent system; but some of them already make use of them, in particular the top patentees among universities. The University of California at Los Angeles sued Genentech for infringing its patent on the gene for human growth hormone, and claimed 4 billion dollars in damages from the biotech company. During the nine years of the procedures, in which the university tried to prove that the drug Protropin was synthesized using the patented gene, it spent 20 million dollars in legal fees alone. The university finally agreed to settle the case for 200 million dollars.[421]

Against this background it appears undeniable that universities have become competitors of biotech companies.[422] The more that universities take over a commercial function, the less they can be seen as disinterested users of patented inventions.[423] The network economy is

[416] OECD (2006), p.12.
[417] Etzkowitz (1997), p.141.
[418] Merges (1996), p.158.
[419] Eisenberg (2006), p.1019.
[420] Walsh (2003), p.1021.
[421] Resnik (2001), p.33.
[422] Resnik (2001), p.52; Guellec (2007), p.77.
[423] Webster (1997), p.54.

giving and taking among equals. And because patents are a legal instrument utilized for economic purposes, there is no reason why one participant in the network shall enjoy the privilege to make use of a privilege against all others, whereas others shall not. Before patent law too, all persons are equal. Consequently, the United States Court of Appeals made it unmistakably clear that there cannot be any research exemption that would apply specifically to universities, even if the patented product is used for experimental purposes only.[424]

Considering the involvement of universities in the networks of knowledge economy, the court's ruling seems inevitable. The case in the United States may now become a precedent for the European Union, because both markets follow the same policy of commercializing scientific research results, particularly in biotechnology. The European Patent Convention contains no explicit research exemption. In the European Union the research exemption is provided for in domestic law,[425] and envisaged in the form of article 9(b) Draft Regulation on the Community patent.[426] Rule 33 EPC allows for issuing samples of deposited biological material for experimental purposes, without however clarifying what the exempted research consists of. Does the exemption only cover experiments done with the material in order to research its characteristics, or does it admit experiments using the material in order to examine other materials? This is relevant for pharmaceutical research where biological material is used to develop a drug, whereby the drug can be manufactured industrially without making use of the biological material.[427] Whether the invention is used in such cases for commercial purposes depends on the interpretation of the unspecified research exemption in European patent law.

The interpretation might be informed by a look at the exceptions from patentability in European patent law. Article 53(a) EPC and rule 28(c) EPC exempt from patentability inventions used for commercial purposes on moral grounds, which in principle permitted their use for experimental purposes. Here, the Enlarged Board of Appeal stated that the use of an invention presupposes its production, and the production is an ordinary stage in the use of something for commercial purposes: the production of an invention remains commercial exploitation, even where there is an intention to use the invention for further research.[428] Thus, the broad scope installed for commercial use of an invention marginalizes the scope of its experimental use. From this one might infer that recourse to the research exemption already is very limited, and occasions for experiments on patented inventions that cannot be related to commercial purposes are scarce.

In the European Union, it is the Member States who warrant the use of patented inventions for experimental purposes without fear of litigation on their territory. This exemption turned out problematic in knowledge economy and will inevitably be contested by global competition watchdog agencies. In the competitive network of knowledge economy the European Union's research exemption may be seen as a subsidy to academic researchers; and academic researchers add value to the network in economic terms, benefiting from their corporate alliances sustained by the patent regime, and thus they are conclusively conceived to be competitors. Therefore, the knowledge researchers produce under the exemption may disadvantage the patent holder commercially; in particular when the holder has no access to the upstream inventions based on the patent because the university itself has patented them.[429]

---

424 *John Madey v. Duke University* 307 F.3d 1351 (2002) 27.
425 Derzko (2003), p.50.
426 Council of the European Union. Working Document 13706/09 PI 92.
427 Gold (2001), p.358.
428 G 2/06 *Use of embryos/WARF* (Enlarged Board of Appeal), para 25.
429 OECD (2006), p.45.

If the research exemption in Europe falls, this necessarily affects research at universities. Research will be hindered for fear of inadvertent patent infringements or because licensing is too extensive and expensive.[430] The tragedy of the anti-commons finds its way into the laboratories of universities. Events related to the strict enforcement of patent rights in the United States foreshadow what researchers in the European Union are going to experience without research exemption. Across the Atlantic a patent on a scarlet fever antitoxin prevented further academic research on the disease.[431] Researchers at universities were reluctant to work on scarlet fever because they feared that their research might inadvertently impinge upon the holder's patent rights. The issue dissolved when antibiotics took over as the preferred means for the medical treatment of streptococcal infections.[432]

Patents rarely stop academic research, but hinder it. Some studies cannot report any hindrance of research projects due to patent rights, whereas others do. Researchers not facing patent constraints are either lucky in getting a license or are successful in inventing around a patented invention; mostly, however, they simply ignore its legal protection.[433] In agricultural sciences, researchers from U.S. universities perceive patents as a significant obstacle to their research.[434] In medical sciences the patent situation seems to be most aggravated. Over a half of a survey's respondents decided not to develop a new clinical genetic test because of existing patents; one quarter even stopped performing clinical genetic tests for fear of patent infringement. It is symptomatic for the decline of the communist norm of free sharing in science, that a remarkable 68% of the hindering patents were held by universities.[435]

To the same extent that universities are affected by the patent regime as their corporate competitors; and to the same extent that universities make use of the patent regime to sue their corporate competitors, they might turn the patent regime against other universities with whom they compete for the fame of scientific discoveries. To this end universities might adopt similar patent strategies like companies. As companies patent widely and thickly in order to hinder attempts of competitors to encroach upon their markets, the very same strategy may become standard in science, too. Though the purpose of granting a patent is not to reserve an unexplored field of research for an applicant,[436] this is exactly what universities might achieve in effect with an inflationary patenting activity in a certain field of research. Patents then served to block rival research groups from exploring the same field.[437] And indeed, some scientists file patent applications to guard their own research activity from being constrained by other scientists from rival institutions.[438] Thus, a patent system without research exemption acerbated the competition on the use of anti-competitive means in science to ensure priority in a field of research. In addition to elaborate attempts made to preserve secrecy and to control a particular field of research through material transfer agreements, patents on minor inventions are suited to impede major scientific results by others, and thus endow the patent holder with even greater control over a field of research, either by way of excluding other researchers in general, or by imposing strict requirements in licensing agreements.

430 OECD (2006), p.5.
431 Weil (1989), p.84.
432 Weiner (1989), p.93.
433 Walsh (2003), p.1021.
434 Eisenberg (2006), p.1018.
435 Cho (2003), p.3.
436 T 870/04 *BDP1 Phosphatase/Max-Planck* (Boards of Appeal), para 25.
437 Mirowski (2004), p.133.
438 Webster (1997), p.57.

In sum, under a patent regime academic scientists become even more careful with disclosing too much: Either because they are tied contractually to a company, or because they want to ensure under entrepreneurial aspects that their publications do no preempt future patent applications.[439] Considering the importance of research results for the development of biotechnological products, any strategic intrigue that replaces cooperation, any commercial incentive that limits the period of cooperation goes to the detriment of economy and society. A patent system that effects a further restriction in the shared use of tools, like gene promoters or markers, or of databases storing the specificities of biological material threatens Europe's competitiveness in biotechnology,[440] and thus runs counter to the paramount policy goal of the European Union.

To date, the effects of the European patent regime on science are rather marginal, because cooperation among researchers is already limited by the boundaries of their private interest in reputation, promotion, and power. The effects on industry are much more severe. The more entangled and intertwined universities become with biotech companies, the more these severe effects will penetrate science, too. And this will be the case, when scientists lose the still valid research exemption in patent law. The research exemption on the other hand suggests at the same time – for economic reasons – the exclusion of universities or academic researchers from the group of persons entitled to file a patent under article 58 EPC. In other words, with the research exemption universities cannot fully participate in the competition of knowledge economy, because they enjoyed a unilateral advantage over corporate competitors. The exemption distorts this competition. That is, with or without the research exemption, universities cannot fulfil the role designated to them in economy. They cannot at the same time side with the freedom of science and the constraints of markets.

439 Webster (1997), p.56.
440 EUR 21459 (2004), p.20.

5 Knowledge revisited

Uncovering knowledge as skills helped clarify and understand patent law, in particular central concepts like ‘innovation’. Innovation in terms of technological progress is to be determined by a skilled person in the technology as inventive step. Thus, skills are decisive whenever there is talk of patenting knowledge. In this context, the essential distinction between knowledge and knowledge products turned out to be equally fruitful. It helped understanding what is patentable, and what the implications for society of something being patented are. And it helped explaining why the EU does not succeed in attaining the policy aims it pursues with patents: to launch an incentive for investments in innovations in exchange for disclosing the knowledge needed to put an invention into practice.

Patent rights are bound to fail attracting investment and disseminating knowledge because they do not break the deadlocked motivation patterns in science and industry, but rather strengthen them. Priority is the dominating incentive for academic and commercial researchers. Consequently, they use patents to ensure priority. These uses do not necessarily promote technological progress or immediate dissemination of research results. Researchers try to ensure priority through exorbitant claims in patent applications, or through fooling patent applications that misguide competitors’ investments in an envisaged innovation. To ensure priority within a patent system, researchers care not to disclose too much in patent applications or in the run-up to patent applications.

Successful, certainly, the EU’s legislated facilitations have been with regard to patenting in the area of biotechnology. However, the Biotech Directive facilitated patenting, not investment in innovations. Economic studies could not establish a link between patents and investment in innovations, nor between patents and innovations. Excessive patenting instead seems to have developed into genuine dynamics of a patent system, disconnected from innovating activities. These dynamics entail enormous sums of patent fees and litigation costs without any sign of a benefit for competition based on innovations.

Competition law is only partly suited to regulate abuse of patents because article 102 TFEU requires a dominant position of abusing companies within the internal market. However, abuse of patents seems endemic, and thus not ascribable to single companies, even dominant companies. The excess of patenting and the accompanying abuse could rather be curtailed by the skilled person when examining a patent application. She could in principle enlarge the inventive step required to get a patent granted. The assessment of the length of an inventive step depends on the knowledge attributed to that person, and thus on science rather than on law. This suggests in terms of innovation that law takes a restrictive function delimiting the exploitation of inventions, rather than an enabling function inducing the creation of new inventions; and it explains why the threats of patent law prevail over its opportunities.

6 References

Adelman, Martin J. et al. (eds). *Patents and technological Progress in a globalized World.* Heidelberg: 2009.

Anderson, Clive. *Patent Nonsense.* London: 1994.

Arai, Hisamitsu. *Intellectual Property for the twenty-first Century.* Geneva: 1999.

Arrow, Kenneth. Economic Welfare and the Allocation of Resources for Invention. In: National Bureau of Economic Research (1962), 609-626.

Arrow, Kenneth. Classificatory Notes on the Production and Transmission of technological Knowledge. In: *American Economic Review 59* (1969), 29-35.

Arundel, Anthony. Measuring the economic Impacts of Biotechnology. In: Mothe (2000), 83-100.

AUTM (The Association of University Technology Managers). *US Licensing Activity Survey.* Deerfield: 2006.

Bains, William. Venture Capital and the European Biotechnology Industry. New York: 2009.

Barton, John H.. Emerging Patent Issues in genomic Diagnostics. In: *Nature Biotechnology 24* (2006), 939-941.

Baumgartner, Christoph. Exclusion by Inclusion? On Difficulties with regard to an effective Assessment of Patenting in the Field of Biotechnology. In: *Journal of Agricultural and Environmental Ethics 19* (2006), 521-539.

Baumol, William J.. *The Free-Market Innovation Machine.* Princeton: 2002.

Beer, Daniel d.. *Brevet, Santé publique et Accès aux Médicaments essentiels.* Brussels: 2008.

Belt, Henk v.d.. 'Mag ik uw Genen even patenteren?' In: *Krisis 2* (2004), 22-37.

Benett, Belinda et al. (eds). *The brave new World of Health.* Sydney: 2008.

Bessen, James; Meurer, Michael J.. *Patent Failure.* Princeton: 2008.

Beuzekom, Brigitte v.; Arundel, Anthony. OECD Biotechnology Statistics 2006. Paris: 2006.

Beuzekom, Brigitte v.; Arundel, Anthony. OECD Biotechnology Statistics 2009. Paris: 2009.

Boldrin, Michele; Levine, David K.. *Against intellectual Monopoly.* Cambridge: 2008.

Boonin, Leonard G.. The University, scientific Research and the Ownership of Knowledge. In: Weil (1989), 253-267.

Borrás, Susana. The Governance of the European Patent System: effective and legitimate? In: *Economy and Society 35* (2006), 594-610.

Bostanci, Adam; Calvert, Jane. Invisible Genes: The Genomics Revolution and patenting Practice. In: *Studies in History and Philosophy of Biology and Biomedical Sciences 39* (2008), 109-119.

Bourdieu Pierre. The Specifity of the scientific Field and the social Conditions of the Progress of Reason. In: *Social Science Information 14* (1975), 19-47.

Boyle, James (ed). *The public Domain.* Durham: 2003.

Boyle, James. The second Enclosure Movement and the Construction of the public Domain. In: Boyle (2003), 33-74.

Boyle, James. Mertonianism unbound? Imagining free, decentralized Access to most cultural and scientific Material. In: Ostrom (2007), 123-144.

Brush, Stephen B.. Indigenous Knowledge of biological Resources and Intellectual Property Rights. In: *American Anthropologist 95* (1993), 653-671.

Bush, Vannevar. *Science: The endless Frontier*. Washington: 1945.

Buttel, Frederick H.; Belsky, Jill. Biotechnology, Plant Breeding, and Intellectual Property. In: Weil (1989), 110-131.

Campbell, Eric G.. Data Withholding in academic Genetics. In: *Journal of the American Medical Association 287* (2002) 473-480.

Carlsson, Bo. A Systems Framework for the Study of Economic and social Dynamics of Biotechnology. In: Mothe (2000), 9-28.

Carruthers, Bruce G.; Ariovich, Laura. The Sociology of Property Rights. In: *Annual Review of Sociology 30* (2004), 23-46.

Chiarella, Pieranna; Fazio, Vito M.. Mouse monoclonal Antibodies in biological Research: Strategies for high-throughput Production. In: *Biotechnology Letters 30* (2008), 1303.

Cho, Mildred K. et al.. Effects of Patents and Licenses on the Provision of clinical genetic Testing Services. In: *Journal of Molecular Diagnostics 5* (2003), 3-8.

Chomsky, Noam et al. (eds). *The Cold War and the University.* New York: 1997.

Christopher, May. *A global political Economy of Intellectual Property Rights.* London: 2000.

Cohen, Jon. Share and share alike isn't always the Rule in Science. In: *Science 268* (1995), 1715-1718.

Cohen, Wesley M.; Levinthal, Daniel A.. A new Perspective on Learning and Innovation. In: *Administrative Science Quarterly 35* (1990), 128-152.

Cohen, Wesley et al. Research and Development Spillovers, Patents, and the Incentive to innovate in Japan and the US. In: *Research Policy 31* (2002), 1349-1367.

Coutinho, Marilia et al.. Intellectual Property and public Research in Biotechnology. In: *Scientometrics 58* (2003), 641-656.

Cox, Robert W.. Social Forces, States, and World Orders. In: *Milennium 10* (1981), 126-155.

Czarnitzki, Dirk et al.. Why challenging the Ivory Tower? New Evidence on the Basicness of academic Patents. ZEW Discussion Paper 09-029 (2009).

Danguy, Jérôme; Pottelsberghe de la Potterie, Bruno v.. Cost-Benefit Analysis of the Community Patent. CEPR Discussion Paper 7631 (2010).

Davis, Michael. Patents, natural Rights, and natural Property. In: Weil (1989), 241-249.

Derzko, Natalie M.. A local and comparative Analysis of the experimental Use Exception. In: *IDEA The Journal of Law and Technology 44* (2003), 1-78.

Dewey, John. The historic Background of corporate legal Personality. In: *Yale Law Journal 35* (1925), 655-673.

Dickinson, Donna. Consent, Commodification and Benefit-Sharing in genetic Research. In: *Developing World Bioethics 4* (2004), 110-124.

Dijstelbloem, Huub; Schuyt, Kees (eds). *De publieke Dimensie van Kennis.* The Hague: 2002.

Doern, Bruce. The contested international Regime for Biotechnology. In: Mothe (2000), 143-160.

Doll, John J.. Biotechnology: The Patenting of DNA. In: *Science 280* (1998), 689-690.

Dommering, Egbert et al.. De Overheid en het publiek Domein van Informatie voor wetenschapelijk Onderzoek. In: Dijstelbloem (2002), 249-303.

Drahos, Peter. Intellectual Property Law and basic Science: Extinguishing Prometheus? In: *Law in Context 56* (1992), 433-455.

Drahos, Peter. *A Philosophy of Intellectual Property.* Dartmouth: 1996.

Drahos, Peter; Braithwaite, John. Intellectual Property, corporate Strategy, Globalisation. In: *Wisconsin International Law Journal 20* (2002), 451-480.

Drahos, Peter; Mayne, Ruth (eds). *Global Intellectual Property Rights: Knowledge, Access and Development.* London: 2003.

Dreier, Thomas; Hugenholtz, Bernt P. (eds). *Concise European Copyright Law.* Dordrecht: 2007.

Drucker, Peter F. (ed). *Harvard Business Review of Knowledge Management.* Harvard: 1998.

Drucker, Peter F.. *The Age of Discontinuity.* 8th ed. New Jersey: 2008.

Eden, Kathy. Friends hold all Things in common: Tradition, Intellectual Property, and the Adages of Erasmus. Yale: 2001.

Eisenberg, Rebecca S.. Proprietary Rights and the Norms of Science in Biotechnology Research. In: *Yale Law Journal 97* (1987), 177-231.

Eisenberg, Rebecca S.; Heller, Michael. Can Patents deter Innovation? The Anticommons in biomedical Research. In: *Science 280* (1998), 698-701.

Eisenberg, Rebecca S.. Patents and Data-Sharing in public Science. In: *Industrial and Corporate Change 15* (2006), 1013-1031.

Eisenberg, Rebecca S.. Biotech Patents: Looking back while moving forward. In: *Nature Biotechnology 24* (2006), 317-319.

Elsmore, Matthew J.. Quality and Quantity: Can we have both in the European Patent System? In: *ERA Forum 10* (2009a), 215-230.

EPO. Guidelines for Examination in the European Patent Office. Munich: 2010.

Etzkowitz, Henry; Leydesdorff, Loet (eds). *Universities and the global Knowledge Economy.* London: 1997.

Etzkowitz, Henry. The entrepreneurial University and the Emergence of democratic Corporatism. In: Etzkowitz (1997), 141-154.

European Commission. Tomorrow's Bio-Society. 11/80. Brussels: 1980.

European Commission. Opinion of the Economic and Social Committee on the 'Proposal for a European Parliament and Council Directive on the legal Protection of biotechnological Inventions'. In: *Official Journal C 295* (07.10.1996).

European Commission. Promoting Innovation through Patents. COM (1997) 314.

European Commission. Inventory of public Biotechnology R&D Programme in Europe. Bruxelles: 1999.

European Commission. European Science and Scientists between Freedom and Responsibility. Luxembourg: 1999.

European Commission. An Assessment of the Implications for basic genetic Engineering Research of Failure to publish Papers. COM (2002) 2.

European Commission. Life Sciences and Biotechnology – A Strategy for Europe. COM (2002) 27.

European Commission. Development and Implications on Patent Law in the Field of Biotechnology and Genetic Engineering. COM (2002) 545.

European Commission. Towards a European Knowledge-based Bioeconomy. EUR 21469 EN. Brussels: 2004.

European Commission. Life Sciences and Biotechnology – A Strategy for Europe. Third Progress Report and future Orientations. COM (2005) 286.

European Commission. Development and Implications on Patent Law in the Field of Biotechnology and Genetic Engineering. COM (2005) 312.

European Commission. More Research and Innovation. COM (2005) 488.

European Commission. Study on the economic and technical Evolution of the scientific Publications Markets in Europe. Brussels: 2006.

European Commission. Enhancing the Patent System in Europe. COM (2007) 165.

European Commission. Mid Term Review of the Strategy on Life Sciences and Biotechnology. COM (2007) 175.

European Commission. A single Market for 21st Century Europe. COM (2007) 724.

European Commission. Taking European Knowledge Society seriously. EUR 22700 EN. Brussels: 2007.

European Commission. Consequences, Opportunities and Challenges of modern Biotechnology for Europe. EUR 22728 EN. Brussels: 2007.

European Commission. Report on Competition Policy 2005. Brussels: 2007.

European Commission. Pharmaceutical Sector Inquiry Report. Brussels: 2009.

Farrelly, Colin. Gene Patents and Justice. In: *The Journal of Value Inquiry 41* (2007), 147-163.

Fikentscher, Wolfgang. Intellectual Property and Competition. In: *International Review of Intellectual Property and Competition Law 2* (2007), 137-165.

Filipkowska, Zofia. Sanitary and bacteriological Aspects of Sewage Treatment. In: *Acta Microbiologica Polonica 52* (2003), 57-66.

Fischmann, Filipe. Die Pflicht zur Lizenzerteilung in Patent-Ambush-Fällen nach deutschem und europäischem Kartellrecht. In: *Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 3* (2010), 185-195.

Fisher, William. Reconstructing the Fair Use Doctrine. In: *Harvard Law Review 101* (1988), 1661-1795.

Fisher, William. *Recent Development in Intellectual Property Law.* Cambridge: 2000.

Fitzgerald, Brian. Theoretical Underpinning of intellectual Property. In: *Canadian Journal of Law and Jurisprudence 16* (2003), 179-189.

Frahm, Katharina; Gebauer, Jochen. Patent auf Leben? In: *Europarecht 1* (2002), 78-95.

Frege, Gottlob. *Logische Untersuchungen.* Göttingen: 1966.

Fries, Jakob F.. *Neue oder anthropologische Kritik der Vernunft.* Heidelberg: 1831.

Galjaard, Hans. Responsibility in Life Sciences. In: European Commission (1999), 69-81.

Gallini, Nancy T.. The Economics of Patents. In: *Journal of Economic Perspectives 16* (2002), 131-154.

Gambardella, Alfonso et al.. The Value of Patents for today's Economy and Society. Final Report: 2006.

Gaudillière, Jean-P.. The Biotechnology Problem in the History of molecular Biology. In: *Studies in History and Philosophy of Biology and Biomedical Sciences 40* (2009), 20-28.

Gibbons, Michael; Johnston, Ron. The Roles of Science in technological Innovation. In: *Research Policy 3/3* (1974), 221-242.

Gmeiner, Robert; Kögeler, Margarethe. Die Patentierung biotechnologischer Erfindungen. In: *ERA Forum 7* (2006), 530-549.

Gold, Richard E.; Gallochat, Alain. The European Biotech Directive: Past as Prologue. In: *European Law Journal 7* (2001), 331-366.

Gold, Richard E. et al.. Needed: Models of Biotechnology Intellectual Property. In: *Trends in Biotechnology 20* (2002), 327-329.

Gold, Richard E. et al.. Gene Patents – more Evidence needed, but Policymakers must act. In: *Nature Biotechnology 25* (2007), 388-389.

Goldman, Alan H.. Ethical Issues in proprietary Restrictions on Research Results. In: Weil (1989), 69-82.

Gottweis, Herbert. *Governing Molecules.* Cambridge: 1998.

Graaff, Maarten V.W.d.. Octrooieerbaarheid van menselijke Genen. Rotterdam: 2004.

Grubb, Philip W.. *Patents for Chemicals, Pharmaceuticals and Biotechnology.* Oxford: 1999.

Guédou, Benjamin. Le Système de Brevet en Europe. In: *Trésor-Éco Lettre 9* (2007), 1-8.

Guellec, Dominique; Pottelsberghe de la Potterie, Bruno v.. *The Economics of the European Patent System.* Oxford: 2007.

Gulbrandson, Magnus. Universities and industrial competitive Advantage. In: Etzkowitz (1997), 121-140.

Gurry, Francis. The Cambrian Explosion. In: *International Review of Industrial Property and Copyright Law 3* (2007), 255-258.

Gutwirth, Serge. *Waarheidsanspraken in Recht en Wetenschap.* Brussels: 1993.

Hagstrom, Warren O.. *The scientific Community.* New York: 1965

Hall, Bronwyn H.. Patents and Patent Policy. In: *Oxford Review of Economic Policy 23* (2007), 568-587.

Hamer, Alex E.. Octrooirecht en Biotechnologie. Rotterdam: 1999.

Hammond, Grant. Quantum Physics, econometric Models and Property Rights to Information. In: *McGill Law Journal 27* (1981), 48-72.

Hegel, Georg W.F.. *Grundlinien der Philosophie des Rechts.* 2nd ed. Frankfurt/M.: 1989.

Henderson, Rebecca et al.. Universities as a Source of commercial Technology. In: Jaffe (2002), 237-260.

Herder, Matthew. Proliferating Patent Problems with human embryonic Stem Cell Research? In: *Bioethical Inquiry 3* (2006), 69-79.

Hettinger, Edwin C.. Justifying intellectual Property. In: *Philosophy and Public Affairs 18* (1989), 31-52.

Hicks, Diana. Published Papers, tacit Competencies and corporate Management of the public/private Character of Knowledge. In: *Industrial and Corporate Change 4/2* (1995), 401-424.

Hildebrandt, Mireille. Wetenschap in Rechte. In: *Tijdschrift voor de Rechterlijke Macht 1* (2004), 187-195.

Hildebrandt, Mireille. The Trial of the Expert: Épreuve and Preuve. In: *New Criminal Law Review 10* (2007), 78-101.

Hughes, Justin. The Philosophy of Intellectual Property. In: *Georgetown Law Journal 77* (1988), 287-366.

Hull, David L.. *Science as a Process.* Chicago: 1988.

Jaffe, Adam B.; Trajtenberg, Manuel (eds). *Patents, Citatations & Innovations.* Cambridge: 2002.

Jaffe, Adam B.; Trajtenberg, Manuel. Flows of Knowledge from Universities and Federal Laboratories. In: Jaffe (2002), 179-198.

Jaffe, Adam B.; Trajtenberg, Manuel. International Knowledge Flows: Evidence from Patent Citation. In: Jaffe (2002), 199-234.

Jaikumar, Ramchandran; Bohn, Roger. The Development of intelligent Systems for industrial Use. In: *Research on Technological Innovation Management and Policy 3* (1986), 182-188.

Jasanoff, Sheila. *The fifth Branch.* Harvard: 1990.

Jasanoff, Sheila. *Designs on Nature.* Princeton: 2005.

Kaul, Inge et al. (eds). *Global Public Goods: International Cooperation in the 21st Century.* New York: 1999.

Keirsblick, Bert et al.. *Facing the Limits of Law.* Heidelberg: 2009.

Kieff, Scott. Property Rights and Property Rules for Commercializing Inventions. In: *Minnesota Law Review 85* (2001), 705-754.

Kinsella, Stephan L.. Against intellectual Property. In: *Journal of Libertarian Studies 15* (2001), 1-53.

Kitcher, Philip. *The Advancement of Science.* New York: 1993.

Kitcher, Philip. *Science, Truth, and Democracy*. Oxford: 2001.

Kneller, Richard. Frontier Technology, Absorptive Capacity and Distance. In: *Oxford Bulletin of Economics and Statistics 67* (2005), 1-23.

Knorr-Cetina, Karin D.. *The Manufacture of Knowledge.* Oxford: 1981.

Kuflik, Artur. Moral Foundations of Intellectual Property Rights. In: Weil (1989), 219-240.

Laudien, Dieter. Die Biopatentrichtlinie in der Praxis: kritische Anmerkungen aus der Sicht von Wirtschaft und Forschung. In: *ERA Forum 7* (2006), 571-586.

Lemin, Alex J.. Patenting Microorganisms: Threats to Openness. In: Weil (1989), 193-199.

Lemley, Mark A.. Ex ante versus ex post Justifications of Intellectual Property. In: *University of Chicago Law Review 71* (2004), 129-149.

Lemmens, Trudo et al.. The Subjectivity of Objectivity: The social, cultural and political Shaping of Evidence-based Medicine. In: Benett (2008), 1-29.

Lerner, Joshua. Patenting in the Shadow of Competitors. In: *Journal of Law and Economics 38* (1995), 463-495.

Lerner, Joshua; Jaffe, Adam B.. Reinventing public Research & Development: Patent Policy and the Commercialization of national Laboratory Technologies. In: Jaffe (2002), 287-376.

Lessig, Lawrence. *Free Culture.* New York: 2004.

Levin, Richard C. et al. Appropriating the Returns from industrial Research and Development. In: *Brookings Papers on Economic Activity 3* (1987), 783-820.

Lewontin, Richard C.. The Cold War and the Transformation of the Academy. In: Chomsky (1997), 1-34.

Liotard, Isabelle. Les Droits de Propriété intellectuelle: Une nouvelle Arme stratégique des Firms. In: *Révue d'Économie Industrielle 89* (1999), 69-84.

Lobato de Faria, Paula. Ownership Rights in Research Biobanks. In: Solbakk (2009), 263-276.

Locke, John. *Two Treatises of Government.* London: 1824.

Loewenheim, Ulrich. Wettbewerbskonforme Gestaltung des Patent- und Gebrauchsmusterrechts. In: *Gewerblicher Rechtsschutz und Urheberrecht 11* (1977), 683-685.

Macdonald, Stuart. Exploring the hidden Costs of Patents. In: Drahos (2003), 13-39.

Macdonald, Stuart. When Means become Ends: Considering the Impact of Patent Strategy on Innovation. In: *Information, Economics and Policy 16* (2004), 135-158.

Machlup, Fritz. Die wirtschaftlichen Grundlagen des Patentrechts I. In: *Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 8/9* (1961), 373-390.

Machlup, Fritz. Die wirtschaftlichen Grundlagen des Patentrechts II. In: *Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 10* (1961), 473-482.

Machlup, Fritz. Die wirtschaftlichen Grundlagen des Patentrechts III. In: *Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 11* (1961), 524-537.

Machlup, Fritz. *Knowledge: its Creation, Distribution, and economic Significance.* Princeton: 1980.

MacKenzie, Michael et al.. Patents and free scientific Information in Biotechnology. In. *Science, Technology and Human Values 15* (1990), 65-83.

Mansfield, Edwin. Academic Research underlying industrial Innovations. In: *Review of Economics and Statistics 77* (1995), 55-65.

Martin, Brian. Against Intellectual Property. In: *Philosophy and Social Action 35* (1995), 1-13.

Maskus, Keith E.. *Intellectual Property Rights in the Global Economy.* Washington: 2000.

Mathijs, Gert. Patenting Genes may slow down Innovation and delay Availability of cheaper genetic Tests. In: *British Medical Journal 329* (2004), 1358-1359.

Maurer, Stephen M.; Scotchmer, Suzanne. Database Protection: Is it broken and should we fix it? In: *Science 284* (1999), 1129-1130.

Merges, Robert P.; Nelson, Richard. On the complex Economics of Patent Scope. In: *Columbia Law Review 90* (1990), 839-891.

Merges, Robert P.. Property Rights Theory and the Commons: The Case of scientific Research. In: *Social Philosophy and Policy 13* (1996), 145-167.

Merton, Robert K. (ed). *The Sociology of Science.* Chicago: 1973.

Metcalfe, Stanley et al.. Networks of Knowledge: the distributed knowledge of medical Innovation. In: *Scientometrics 70* (2007), 459-489.

Metcalfe, Stanley; Ramlogan, Ronald. Limits of the Economy of Knowledge and Knowledge of the Economy. In: *Futures 37* (2005), 655-674.

Mirowski, Philip. *The effortless Economy of Science?* Durham: 2004.

Mohnen, Pierre. Innovation and Intellectual Property Values. In: *Journal of Technology Transfer 34* (2009), 121-127

Moore, Adam D. Intellectual Property: Theory, Privilege, and Pragmatism. In: *Canadian Journal of Law and Jurisprudence 16* (2003), 191-216.

Moser, Petra. How do Patent Laws influence Innovation? In: *American Economic Review 95* (2003), 1215-1236.

Mothe, John d.l.; Niosi, Jorge (eds). *The Economics and social Dynamics of Biotechnology.* Dordrecht: 2000.

Murray, Fiona; Jensen, Kyle. Intellectual Property Landscape of the Human Genome. In: *Science 310* (2005), 239-240.

Murray, Fiona; Stern, Scott. Do formal Intellectual Property Rights hinder the free Flow of scientific Knowledge? In: *Journal of Economic Behavior and Organization 63* (2007), 648-687.

National Bureau of Economic Research. *The Rate and Direction of inventive Activity.* Cambridge: 1962.

National Research Council. *Reaping the Benefits of genomic and proteomic Research.* Washington: 2006.

Nelson, Richard R.. The simple Economics of basic scientific Research. In: *Journal of political Economy 67/3* (1959), 297-306.

Nelson, Richard R.. Reflections on 'The simple Economics of basic scientific Research'. In: *Industrial and Corporate Change 15* (2006), 903-917.

Nenow, Lydia. To patent or not to patent: The European Union's new Biotech Directive. In: *Houston Journal of International Law 23* (2001), 569-607.

Neukom, John. A prior use Right for the Community Patent Convention. In: *European Intellectual Property Rights Review 12* (1990), 165-169.

Nimmer, Raymond T.; Krauthaus, Patricia. Information as Commodity: New Imperatives of Commercial Law. In: *Law and Contemporary Problems 55* (1992), 103-130.

Nonaka, Ikujiro. The Knowledge-creating Company. In: Drucker (1998), 21-45.

Nordhaus, William D.. An economic Theory of technological Change. In: *American Economic Review 59* (1969), 18-28.

Nozick, Robert. *Anarchy, State, and Utopia.* New York: 1974.

Nuffield Council of Bioethics. *The Ethics of Patenting DNA.* London: 2002.

OECD. Research Use of patented Knowledge. Paris: 2006.

OECD. Guidelines for the Licensing of genetic Inventions. Paris: 2006.

OECD. Intellectual Property Issues in Biotechnology: Health and Industry. Paris: 2007.

OECD. The Bioeconomy to 2030. Paris: 2009.

OECD. Guidelines for a harmonised statistical Approach to Biotechnology. Paris: 2009a.

Oldham, Paul; Cutter, Anthony M.. Mapping global Status and Trends in Patent Activity for biological and genetic Material. In: *Genomics, Society and Policy 2* (2006), 62-91.

Oliver, Amalya L. *Networks for Learning and Knowledge Creation in Biotechnology.* Cambridge: 2009.

Osterrieth, Christian. Patent-Trolls in Europa – braucht das Patentrecht neue Grenzen? In: *Gewerblicher Rechtsschutz und Urheberrecht 6* (2009), 540-545.

Ostrom, Elinor; Hess, Charlotte (eds). *Understanding Knowledge as a Commons.* Cambridge: 2007.

Overwalle, Geertrui v.; Zimmeren, Esther v.. Functions and Limits of Patent Law. In: Keirsblick (2009), 416-442.

Owen, Robert. The human growth Hormone Creutzfeld Jakob Disease Litigation. In: *The Medico-Legal Journal 65* (1997), 46-64.

Owen-Smith, Jason; Powell, Walter W.. The expanding Role of University Patenting in the Life Sciences. In: *Research Policy 32* (2003), 1695-1711.

Park, Frank et al.. Therapeutic Levels of human Factor VIII and IX using HIV-1-based lentiviral Vectors in Mouse Liver. In: *Blood 96* (2000), 1173-1176.

Pattinson, Bill et al.. Internationally comparable Indicators of Biotechnology. In: Mothe (2000), 135-142.

Peirce, Charles S.. *How to make our Ideas clear?* Frankfurt/M.: 1968.

Polanyi, Michael. *Personal Knowledge.* London: 1958.

Popper, Karl R.. *Objektive Erkenntnis.* Hamburg: 1993.

Posner, Richard A.; Landes, William. An economic Analysis of Copyright Law. In: *Journal of Legal Studies 18* (1989), 325-363.

Posner, Richard A. The Law and Economics of Intellectual Property. In: *Dædalus 131* (2002), 5-12.

Pretnar, Bojan. Die ökonomischen Auswirkungen von Patenten in der wissensbasierten Marktwirtschaft. In: *Gewerblicher Rechtsschutz und Urheberrecht Internationaler Teil 9* (2004), 776-786.

Rai, Arti K. Regulating scientific Research: Intellectual Property Rights and the Norms of Science. In: *Northwestern University Law Review 94* (1999), 77-152.

Rai, Arti K.; Eisenberg, Rebecca S.. Bayh-Dole Reform and the Progress of Biomedicine. In: Boyle (2003), 289-314.

Rai, Arti K.; Boyle, James. Synthetic Biology: caught between Property Rights, the public Domain, and the Commons. In: *Public Library of Science Biology 5* (2007), 389-393.

Raitt, Fiona E.. A new Criterion for the Admissibility of scientific Evidence? In: Reece (1998), 153-174.

Ray, Prasun et al.. Effects of Coal Ash on Growth and Metal Uptake by some selected ectomycorrhizal Fungi in vitro. In: *International Journal of Phytoremediation 7* (2005), 199-216.

Reece, Helen (ed). *Law and Science.* Oxford: 1998.

Reed, Esther D. Property Rights, Genes, and Common Good. In: *Journal of Religious Ethics 34* (2006), 41-67.

Reichman, Jerome H.. From Free Riders to Fair Followers: Global Competition under the TRIPS Agreement. In: *New York University Journal of International Law and Politics 1-2* (1997), 11-93.

Reichman, Jerome H.; Uhlir, Paul F.. A contractually reconstructed Research Commons for scientific Data in a highly protectionist intellectual Property Environment. In: Boyle (2003), 315-462.

Resnik, David B.. DNA Patents and scientific Discovery and Innovation. In: *Science and Engineering Ethics 7* (2001), 29-62.

Rosenberg, Alex. On the Priority of Intellectual Property Rights, especially in Biotechnology. In: *Politics, Philosophy and Economics 77* (2004), 77-95.

Rosenberg, Nathan. Science, Invention and economic Growth. In: *Economic Journal 84/333* (1974), 90-108.

Russell, Bertrand. *An Inquiry into Meaning and Truth.* 6th ed. London: 1961.

Ryan, Michael P.. *Knowledge Diplomacy.* Washington: 1998.

Ryle, Gilbert. Knowing how and knowing that. In: *Proceedings of the Aristotelian Society 46* (1945), 1-16.

Samuelson, Paul. The pure Theory of public Expenditure. In: *Review of Economics and Statistics 36* (1954), 387-389.

Scheffler, Dietrich. Monopolwirkung und Informationsfunktion von Patenten aus heutiger Sicht. In: *Gewerblicher Rechtsschutz und Urheberrecht 11* (1989), 798-802.

Schmidt, Christian. Die zwei Paradoxien des geistigen Eigentums. In: *Deutsche Zeitschrift für Philosophie 52* (2004), 755-772.

Schmookler, Jacob. *Invention and economic Growth.* Cambridge: 1966.

Schumpeter, Joseph. The Instability of Capitalism. In: *Economic Journal 38/151* (1928), 365-386.

Sellenthin, Mark O.. *Who should own University Research?* Östersund: 2004.

Sen, Amartya. *The Idea of Justice.* London: 2009.

Senker, Jacqueline. Biotechnology: scientific Progress and social Progress. In: Mothe (2000), 53-69.

Shapiro, Carl. Patent System Reform: Economic Analysis and Critique. In: *Berkeley Technology Law Review 19* (2004), 1017-1048.

Shavell, Steven; Ypersele, Tanguy v.. Rewards versus Intellectual Property Rights. In: *Journal of Law and Economics 44* (2001), 525-547.

Solbakk, Jan H. et al. (eds). *The Ethics of Research Biobanking.* Heidelberg: 2009.

Solla Price, Derek J. d. *Little Science, Big Science.* New York: 1963.

Solla Price, Derek J. d. Is Technology historically independent of Science? In: *Technology and Culture 6/4* (1965), 553-568.

Spence, Michael. The Learning Curve and Competition: In: *The Bell Journal of Economics 12* (1981), 49-70.

Stehr, Nico. Knowledge, Markets and Biotechnology. In: Mothe (2000), 205-214.

Steinvorth, Ulrich. Natürliche Eigentumsrechte, Gemeineigentum und geistiges Eigentum. In: *Deutsche Zeitschrift für Philosophie 52* (2004), 717-738.

Stiglitz, Joseph E.. Knowledge as a global Public Good. In: Kaul (1999), 308-325.

Stiglitz, Joseph E.. Towards a pro-Development and balanced Intellectual Property Right. Keynote Address at the Ministerial Conference of WIPO. Seoul: 2004.

Stiglitz, Joseph E.; Sen, Amartya; Fitoussi, Jean-P. Report by the Commission on the Measurement of economic Performance and social Progress. Paris: 2009.

Suizhuang, Yang. Advance on Study of molecular Marker, Gene Location and Gene Engineering in Draught Resistance in Wheat. In: *Chinese Agricultural Science Bulletin 4* (2007), 59-67.

Tinbergen, Jan. *Shaping the World Economy.* New York: 1962.

Trajtenberg, Manuel. A Penny for your Quotes: Patent Citations and the Value of Innovations. In: Jaffe (2002), 25-50.

Trajtenberg, Manuel et al.. University versus corporate Patents: A Window on the Basicness of Inventions. In: Jaffe (2002), 51-88.

Tsioumanis, Asterios et al.. Is Policy towards intellectual Property Rights addressing the real Problems? In: *Journal of Agricultural and Environmental Ethics 16* (2003), 605-616.

Urso, Giuliana et al. Knowledge Sharing is Power. In: *Transitional Studies Review 16* (2009), 352-367.

Waldron, Jeremy. Property, Justification and Need. In: *Canadian Journal of Law and Jurisprudence 6* (1993), 185-215.

Walsh, John P. et al.. Working through the Patent Problem. In: *Science 299* (2003), 1021.

Washburn, Jennifer. *University Inc., the corporate Corruption of higher Education.* New York: 2005.

Watzlawick, Paul. *Pragmatics of human Communication.* New York: 1967.

Webster, Andrew; Packer, Kathryn. When Worlds collide: Patents in Public-Sector Research. In: Etzkowitz (1997), 47-59.

Weil, Vivian; Snapper, John W. (eds). *Owning scientific and technical Information.* Rutgers: 1989.

Weiner, Charles. Patenting and academic Research. In: Weil (1989), 87-109.

Wilson, James. Could there be a Right to own intellectual Property? In: *Law and Philosophy 28* (2009), 393-427.

Winter, Sidney G.. Patents in complex Contexts: Incentives and Effectiveness. In: Weil (1989), 41-60.

WIPO. Introduction to intellectual Property. Dordrecht: 2006.

WIPO. Impact of the Intellectual Property System on economic Growth. Report 2007.

Wittgenstein, Ludwig. *Philosophische Untersuchungen.* 7th ed. Frankfurt/M.: 1990.

World Bank. Building Knowledge Economies. Washington: 2007.

Wynne, Brian; Smith, Roger (eds). *Expert Evidence.* London: 1989.

Wynne, Brian. Establishing the Rules of Laws. In: Wynne (1989), 23-55.