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Back to the Garden of the Hesperides?

Patent Rights, Competition Law and Human Stem Cells

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“Statutory Declaration

I hereby declare that the thesis has been written by myself without any external unauthorised help, that it has been neither presented to any institution for evaluation nor previously published in its entirety or in parts. Any parts, words or ideas, of the thesis, however limited, and including tables, graphs, maps etc., which are quoted from or based on other sources have been acknowledged as such without exception.”

14507 words

Medical miracles do not happen simply by accident.
They result from painstaking and costly research,
from years of lonely trial and error,
much of which never bears fruit.

Barack Obama's Speech On Stem Cell Executive Order

ABSTRACT (478 words)

The subject of this thesis is the application of the so-called essential facilities doctrine in European Union law against the special features of the biotechnology industry and, more specifically, research with human stem cells.

Human stem cell research is a field traditionally isolated from the protection of patent rights because of ethical concerns. The Biotech Directive contains a "moral exception" clause to patentability which used to be interpreted by the ECJ in broad terms. However, the recent judgment of the ECJ in *ISCC* opens the possibility of granting patents for inventions derived from a specific method of human stem cell research: parthenogenesis. The grant of such patent encourages undertakings to invest in this promising field of biotechnology. The perspective of having a temporary legal monopoly and its potential benefits is especially strong when a patent is granted for a product that can be the basis of numerous cures and therapies for different diseases.

However, if the holder of such a patent decides not to supply parthenotes and refuses to give licenses for their production or use, the development in this field could be seriously harmed. The essential facilities doctrine gives the competitors the possibility to have access to the patent in exchange of an adequate compensation. The base for this doctrine, originating in US, is the principle of obligation to supply emanating from article 102 TFEU. In EU law, the obligation to supply has been assimilated to the obligation to grant licenses for products protected by intellectual property rights.

This doctrine allows access to private property and, therefore, has been the subject of strong criticism from both economic and legal points of view. However, its application is very exceptional. After a controversial evolution of the case law of the ECJ, the circumstances established for its application are the essentiality of the input, the elimination of effective competition in a downstream market and the blockage of a new product or a technical development with potential consumer demand. The rationale

behind this doctrine is precisely to ensure competition, and therefore a variety of prices and products for the consumers.

The criticisms are related to a possible deterrence of innovation. The process of research in this industry is long and expensive, and the investor would expect exclusive rights for the exploitation of the results of his efforts. The application of this doctrine would discourage the investor and, therefore, some new products will never reach the market with equally harmful effects for the consumers.

In conclusion, the essential facilities doctrine can be theoretically applied to the field of human stem cell research. The possible negative effects could be reduced or eliminated with clear criteria which would prevent the reduction of investments just because of its potential application. And, as a result, the patent holder would have enough information to determine what will be the results of refusing access to an essential facility.

KEY WORDS

Abuse of dominant position, biotechnology, competition, compulsory licensing, essential facilities, healthcare, human stem cells, intellectual property rights, morality exception clause, parthenotes, patent.

TABLE OF CONTENTS

INTRODUCTION

In Greek mythology, the Garden of the Hesperides belonged to Hera, Queen of the Gods. In this garden there were trees that bore golden apples. According to the myth, these fruits could give immortality to anyone who ingested them. The Hesperides, daughters of the titan Atlas, and a dragon with hundred heads guarded the garden. Heracles' Eleventh labour was to obtain one of these apples. As Hera was not willing to supply golden apples to Heracles and the defences were extremely difficult to circumvent, Heracles had to ask for the help of Atlas. Thanks to him, Heracles could finish this mission in order to compensate his previous crimes.

What is the similarity of this myth to the subject of this thesis: patent rights, competition law and human stem cells? Human stem cells are here the golden apples: essential products with a huge potential for regenerative medicine. The patent right holder here would be Hera, legal owner of the golden apples. And finally, the anticompetitive behaviour consists in the refusal to supply of Hera to a potential competitor, Heracles. Who is Atlas? The European Commission (hereinafter, EC), the authority that helps the undertaking to obtain a supply or a license for the essential input.

The question that will drive this thesis is as follows: can a refusal to grant a license for patents protecting induced pluripotent stem cells (hereinafter, iPSCs) be considered as an abuse of dominant position under article 102 TFEU? In order to answer this question and give a solution for a potential abuse of dominant position, this thesis will be divided in three parts. First, what are the issues surrounding the patentability of human stem cells? Here, the recent judgment of the European Court of Justice (hereinafter, ECJ) in *International Stem Cell Corporation* is vital, as it opens the door for patents in this field and therefore the competition law issues. Second, what the different positions are of the relation between intellectual property rights and competition in case law, especially in relation to the doctrine of the essential facilities. And finally, the third chapter is dedicated to the application of this doctrine to the field of human stem cell research. This analysis will aim at giving a motivated answer to the research question: the refusal

to supply would indeed constitute an abuse of dominant position, and the essential facilities doctrine could be a genuine tool to eliminate this abuse.

PART I: HUMAN STEM CELLS AND PATENTABILITY

Chapter 1. Understanding human stem cell research: scientific background

Prior to the analysis of patentability and competition law issues surrounding human stem cell research, the most common scientific concepts will be briefly defined in order to facilitate the reading and understanding of this research. After these definitions, an overview of the practical applications of human stem cell research will stand out the importance of a clear legal approach to this subject.

1. Basic concepts and typologies of human stem cells

Human stem cells are defined as "primitive cells with the capacity to divide and give rise to more identical stem cells or to specialize and form specific cells of somatic tissues"[1]. As a result, they are capable of renewing themselves or to evolve into a different cell with a specialised function, such as a muscle cell or a brain cell. Nowadays, three different groups of human stem cells are commonly recognised[2] (ANNEX I):

- *Human embryonic stem cells* (hESC). These cells have unlimited potential to produce any specialised cells of the body, which suggests enormous possibilities for disease research and for providing new therapies.

- *Adult stem cells* (or tissue stem cells). They are derived from fetal or adult tissues. Usually, they can only give rise to the cells of that tissue. In some

[1]G. WERT and C. MUMMERY, "Human embryonic stem cells: research, ethics and policy", (2003) 18 *Human Reproduction*, p. 672.
[2]C. COX, "Types of stem cells and their current uses", (2012) *EuroStemCell*. Available at: http://www.eurostemcell.org/factsheet/stem-cell-research-therapy-types-stem-cells-and-their-current-uses#es (Last accessed 21 April 2016).

tissues, these cells sustain turnover and repair throughout life. For example, stem cells that are found in the skin will produce new skin cells, ensuring that old or damaged skin cells are replenished.

- *Induced pluripotent stem cells* (iPSC). This recent category consists on adult stem cells "reprogrammed" into cells that behave like hESC (parthenotes). This category, with an enormous potential for disease research and drug development, will be especially analysed during this Master's Thesis thanks to the recent case law related to its patentability.

The previous categorisation based on the source of the cell is the most important in order to understand this research. However, the terminology used both by case law and doctrine makes necessary to define also the different types of stem cells according to their potential of development[3]:

- *Totipotent* cells, which are sufficient to form entire organism. A zygote is the most common type of stem cell.

- *Pluripotent* cells, which are able to form all the body's lineages. Embryonic stem cells and parthenotes are examples of this category.

- *Multipotent* cells, which can form multiple mature cell types that constitute an entire tissue or tissues. This is the case of blood stem cells, among others.

- Finally, *unipotent* cells form a single mature cell type. The clearest example is the spermatogonial stem cell, as it can only form sperm cells.

[3] *Ibid*. Annex I illustrates the differences between these different types of cells.

2. Practical applications of human stem cells.

Human stem cells constitute a world of possibilities for the healthcare system. David Warburton, one of the most important experts on stem cell and regenerative medicine, outlines the potential impact of stem cell technology on the pharmaceutical sector: "In about 20 years' time we will have stem cell banks just like we now have pharmacies with medicines in them. You'll get a diagnosis for a specific problem and be given stem cells to treat that problem. Genomic research is going to apply stem cell research not only to a specific disease but to a specific person with a disease […]. You're going to have personalised regenerative medicine"[4].

In more specific terms, the rational use of human stem cells in the medical area and their therapeutic benefits includes the fight against[5] (ANNEX II):

- Autoimmune diseases: arthritis, sclerosis, Crohn's disease and diabetes.
- Neurological disorders: Parkinson's disease, Huntington's disease and strokes.
- Muscle and cartilage degenerations.
- Heart failures.
- Ocular surface diseases.
- Liver diseases.
- Cancer: especially renal, breast, colorectal, ovarian, lung cancers and leukemia.

In this sense, human stem cells "may be used to construct diseases models and to screen effective and safe drugs, as well as to treat patients through the cell transplantation therapy"[6]. The potential benefits for society have no borders and, for this reason, the

[4] The Telegraph, **"**Stem cell 'pharmacies' in the high street in 20 years, predicts expert", 12 July 2010. Available at:
http://telegraph.co.uk/news/science/science-news/7883978/Stem-cell-pharmacies-in-the-high-street-in-20-years-predicts-expert.html (Last Accessed 21 April 2016).
[5] D. LODI, T. IANNITTI and B. PALMIERI, "Stem cells in clinical practice: applications and warnings", (2011) *Journal of Experimental & Clinical Cancer Research*, pages 6-12.
[6] *Ibid.*, p. 12.

thesis will be focused on the legal problems which can obstruct the development of this promising scientific field.

Chapter 2. Patentability of human stem cell research.

The protection of biotechnological inventions with patents, in this case derived from stem cell research, has not received uniformed treatment neither in US nor in Europe ever since the technique was created. The issues arises in the US principally because of technical elements (if the isolation of human stem cells is obvious or not) while in Europe is more related to ethical concerns[7]. This chapter will be dedicated to the legal evolution of the patentability of stem cells. This evolution, in its last step, will allow the analysis of the interplay between patents and competition law.

1. First patents in the United States.

A bath in the city of Syracuse was the scenario of one of the most important advances in Science. In the 3rd century BC, Archimedes pronounced there the famous expression "Eureka" after he realised that the volume of water displaced must be equal to the volume of the part of the submerged body. The applications of this simple discovery are extremely valuable, especially in maritime transport. In the late 1990s, the University of Wisconsin was about to be the scenario of another revolutionary development of Science. Dr. James Thomson and his team could finally isolate human embryonic stem cells derived from *in vitro* fertilization embryos publishing the results of their research in 1998[8].

Three years before the publication of their invention, in 1995, this group of scientists had already applied for a patent on primate embryonic stem cells. It did not have any human exemplar. However, in 1996 the Wisconsin Alumni Research Foundation (WARF) filed another patent specifically for the human embryonic stem cells based on the idea of Thomson. As a result, both patents were concurrently granted. Thanks to the

[7] A. PLOMER, *Patents, Human Rights and Access to Science*, Cheltenham, Edward Elgar, 2015, p. 20.
[8] *Ibid.*, p. 13.

potential of human stem cells and the profits obtained by royalties[9], WARF was able to expand the activity to Europe. In the following lines, WARF is going to have a leading role in the debates analysed by this thesis.

2. The "moral exception" clause in the Biotechnology Directive: evolution of the case law

Articles 6.1 and 6.2 (c) of the Directive 98/44/EC on the legal protection of biotechnological inventions (hereinafter, Biotech Directive) provide that[10]:

> "1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.
> 2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:
> (c) uses of human embryos for industrial or commercial purposes;"

In the same line, article 53 (a) of the European Patent Convention[11] (hereinafter, EPC) contains a "moral exception" clause. This Convention, which is not part of the EU legal order, is extremely important for this topic because the evolution of the protection of intellectual property rights (hereinafter, IPR) in Europe depends on her application by the European Patent Office (hereinafter, EPO). For the purpose of this thesis, which is not focused on the institutional system of patent protection in Europe but on its

[9] For a description of the problematic with the patents of WARF in the US, see A. PLOMER, *supra* note 7, pages 12-19. For an analysis of this provision from an ethical point of view, see A. SCORDAMAGLIA, "Patenting human sem cells under EC patent law – *the ethical dimension*", (supervision of Prof. H. ULLRICH), Bruges, 2006.
[10] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, [1998] O.J. L213/1.
[11] European Patent Convention of 5 October 1973 as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000.

consequences from a competition law perspective, both the EU legal order and the EPC system will be treated jointly[12].

The "moral exception" clause has blocked the grant of patents to inventions derived from human stem cell research for a long time[13]. However, recent evolutions in science followed by case law have partially opened the door to the patentability of these inventions[14]. The initial interpretation of this clause has certainly evolved from the WARF case to the ruling of the ECJ in *International Stem Cell Corporation* (*ISCC*). This new approach will allow studying the current possibility of obtaining a patent and using it in infringement of EU competition law.

a) WARF: first contact between human stem cells and patents in Europe

In 1996, the Wisconsin Alumni Foundation (WARF) filed an application before the EPO related to primate embryonic stem cells (including hSCs) and the process necessary for their reproduction. During the proceedings, the question was whether such inventions fell under the scope of application of the "morality exception" clause which prohibits the patentability of "uses of human embryos for industrial or commercial purposes".

In first instance, the Examining Division applied articles 53 (a) and 28 (c) EPC coming down "in favour of a broad construction of morality-based exceptions to patentability"[15]. The Board of Appeal confirmed this construction with the following words:

> "A claimed new and inventive product must first be made before it can be used. Such making is the ordinary way commercially to exploit the claimed invention

[12] Annex III illustrates the European system of protection of patents.
[13] A. NORDBERG and T. MINSSEN, "A ray of hope for European stem cell patents or out of the smog into the fog?: An analysis of recent European case law and how it compares to the US", (2016) 47 *International Review of Intellectual Property and Competition Law*, p. 23.
[14] *Ibid.*
[15] S. STECKX and J, COCKBAIN, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries*, New York, Cambridge University Press, 2012, p. 280.

and falls within the monopoly granted, as someone having a patent application with a claim directed to this product has on the grant of the patent the right to exclude others from making or using such product. Making the claimed product remains commercial or industrial exploitation of the invention even where there is an intention to use that product for further research. On the facts which this Board must assume in answering the referred question 2, *making the claimed product involves the destruction of human embryos*. This use involving destruction is thus an integral and essential part of the industrial or commercial exploitation of the claimed invention, and thus violates the prohibition of Rule 28(c)"[16].

Under this statement, in the case of an invention produced by a method which initially implies the destruction of a human embryo, and afterwards the production does not require further destruction of human embryos once the patent application has been filed, patentability should not be precluded[17]. This possibility was confirmed in practice by the EPO: "it has been a practice of the EPO to allow patents on stem cell inventions under circumstances where the inventions can be put into practice at the filing date without requiring the destruction of human embryos, for example if the inventions are based on human stem cells which have been grown in the laboratory"[18].

b) Brüstle: one step forward and two steps backwards?

Although the EPO in *WARF* did not give a restrictive interpretation of the "moral exception" clause, it opened the possibility to obtain patents on inventions that did not "directly" require the destruction of a human embryo[19]. Within the EU legal order, however, the exception was constructed quite differently by the ECJ. In the

[16] Decision of the Enlarged Board of Appeal, 25 November 2008, G 2/06, paragraph 25. Emphasis added.
[17] STECKX and COKBAIN, *supra* note 15, p. 287.
[18] P. WEBBER, "Stemmed Potential", *Dehns: Patent and Trade Mar Attorneys*, 12 January 2012. Available online at: http://www.dehns.com/site/information/dehns_articles/stemmed_potential.html (Last Accessed 21 April 2016).
[19] For a deep analysis of this position of the EPO, see M. PATON and A. DENOON, "The Ramifications of the Advocate General's Opinion in the Oliver Brüstle Case", (2011) 33 (9) *European Intellectual Property Review*, pages 590-596.

Brüstle case, the question was similar to the one presented to the EPO previously. Oliver Brüstle filed a patent in Germany related to human embryonic stem cells. Specifically, the patent included neuronal precursor cells, a method for their production and their therapeutic use. Taking into account the opposition of Greenpeace based on the "morality exception" clause, the national court decided to introduce a preliminary reference asking for an interpretation of article 6.2 (c) of the Biotech Directive.

The ECJ adopted in *Brüstle* an interpretation of the patents' "moral exception" clause for use in commercial or industrial purposes which has also been considered as broad[20]: "Article 6(2)(c) of the Directive excludes an invention from patentability where the technical teaching which is the subject-matter of the patent application requires the prior destruction of human embryos or their use as base material, *whatever* the stage at which that takes place and *even if the* description of the technical teaching claimed does not refer to the use of human embryos"[21]. In relation to the concept of human embryo, it provides another wide interpretation[22]: "any human ovum after fertilisation, any non-fertilised human ovum into which the cell nucleus from a mature human cell has been transplanted and any non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis constitute a 'human embryo' within the meaning of Article 6(2)(c) of the Directive"[23].

In clear terms, the ECJ excluded parthenotes from patentability, those being created by a variety of scientific techniques which are capable of cell division even in the absence of sperm fertilisation. In the same line, the judgment also rejects the use of publicly available stem cells lines, so the method would not imply a *de novo* destruction of human embryos. This approach caused great concerns in the scientific community and criticism in the legal literature. As a result, the EPO closed the possibility opened in *WARF* to obtain patents when the invention does not imply a *de novo* destruction of

[20] NORDBERG and MINSSEN, *supra* note 13, p. 5.
[21] Judgment in *Olivier Brüstle v Greenpeace e.V,* C-34/10, ECLI:EU:C:2011:669, paragraph 52. Emphasis added.
[22] NORDBERG and MINSSEN, *supra* note 13.
[23] Judgment in *Olivier Brüstle v Greenpeace e.V*, ECLI:EU:C:2011:669, paragraph 38.

human embryos but the use of publicly available hESC, applying the exception to "'inventions which make use of hESC's obtained by de novo destruction of human embryos *or of publicly available hESC's lines* which were initially derived by a process resulting in the destruction of the human embryo"[24]. As a result, this judgment practically closed the possibility of obtaining protection based on intellectual property (hereinafter, IP) in the field of human stem cell research.

c) International Stem Cell Corporation: back at the right path?

In 2012, the UK Intellectual Property Office (UKIPO) rejected two applications concerning parthenogenesis[25] due to the pronouncement of the ECJ in *Brüstle*[26]. The applicant, International Stem Cell Corporation (hereinafter ISCC), argued that *Brüstle* should not be applied here as soon as parthenotes cannot develop independently into a human being: "parthenogenetically-activated oocyte, which contains only maternal DNA […] cannot ever develop to term, i.e. to provide a viable human being, and neither the activated oocyte, nor any of the cells produced by its division, are totipotent – they are only pluripotent and cannot give rise to placental tissue. In contrast, in the first few cycles of cell division (before blastocyst formation), the cells of a human embryo derived from a fertilised ovum are totipotent"[27].

Consequently, the negative Decision of the UKIPO[28] was appealed before the High Court of Justice of England and Wales. During the proceedings there was no discussion about the fact that parthenogenesis allows the activation of the oocyte by chemical an

[24] Guidelines for Examination in the European Patent Office (November 2014), Part G, Chapters II-17 to 18 on R 28 (c). Emphasis added.
[25] Application GB0621068.6 "Parthenogenetic activation of oocytes for the production of human embryonic stem cells", 23 January 2006; and Application GB0621069.4 "Synthetic cornea from retinal stem cells", 23 October 2006.
[26] Decision of the UK Intellectual Property Office BL O/316/12, 16 August 2012, paragraphs 55-72.
[27] *Ibid.*, paragraph 37.
[28] The Hearing Officer illustrates the scientific approach in Brüstle with the following words in paragraph 63 of the Decision: "the development process from an oocyte to a human is like a journey on a train which is passing through a tunnel. The entrance into the tunnel is activation of the oocyte in some way (i.e., by parthenogenesis or fertilisation), the exit from the tunnel is the development of a viable human being. All the intermediate steps in the development from activated oocyte to human being occur within this tunnel".

electrical techniques without the use of sperm[29]. Due to the lacking of this paternal DNA, parthenotes are merely pluripotent cells unable to develop into a human being. However, the ECJ had expressly rejected the patentability of parthenotes and inventions derived from it[30].

The English Court, taking into consideration the scientific facts presented above, had certain concerns about the validity of the scientific data used by the ECJ in *Brüstle* in order to exclude the patents related to parthenotes[31]. In fact, the preliminary view of the English judge was completely supportive of the position of ISCC[32]. Therefore, the next question was referred to the ECJ: "Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term "human embryos" in Article 6(2)(c) of Directive 98/44/EC on the legal protection of biotechnological inventions?" [33].

Following the opinion of the Advocate General[34], the ECJ established that for the purposes of article 6.2 (c) of the Biotech Directive "an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis does not constitute a 'human embryo' within the meaning of that provision, if, in the light of current scientific knowledge, that ovum does not, in itself, have the inherent capacity of developing into a human being, this being a matter for the national court to determine"[35]. Thanks to this test of inherent capacity proposed by the Advocate

[29] *International Stem Cell Corporation v Comptroller General of Patents* [2013] EWHC 807 (Ch), 17 April 2013, paragraphs 10-22.
[30] Judgment in *Olivier Brüstle v Greenpeace e.V*, ECLI:EU:C:2011:669, paragraph 39.
[31] In particular, the English judge considers that "This factual matrix is different to that before the CJEU in *Brüstle*. In particular, genomic imprinting means that in contrast to a fertilised ovum, there are no totipotent cells present in a parthenote, even in the first few cell divisions after activation. On the current state of knowledge in the art, despite the superficial similarities in initial development highlighted in the UK government's observations and the reference from the Bundesgerichtshof, parthenotes and fertilised ova are **not** identical at any stage", *International Stem Cell Corporation.*, *supra* note 29, at 53.
[32] "I agree with ISCC that if the process of development is incapable of leading to a human being, as the Hearing Officer has found to be the case in relation to parthenotes, then it should not be excluded from patentability as a human embryo […]. I note that totipotent cells are expressly referred to in recital 38 as an example of cells which are obviously excluded from patentability. This would seem surprising, if the intention of the legislation is to exclude pluripotent cells as well", *Ibid.*, paragraphs 55-56.
[33] *Ibid.*, paragraph 59.
[34] Opinion of AG Cruz Villalón in Case C-364/13, *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks,* delivered on 17 July 2014.
[35] Judgment in *International Stem Cell Corporation v Comptroller General of Patents, Designs and Trade Marks*, C-364/13, ECLI:EU:C:2014:2451, paragraph 38.

General, the ECJ was able to change the previous approach against parthenotes based on the written observations presented in Brüstle defending that "an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis did have the capacity to develop into a human being"[36].

This new ruling seems to go on the right path, adapting the legal fiction of *Brüstle* to reality and opening new possibilities for the patentability of hESC despite of the fact that some questions remain "open for debate"[37]. The best evidence to confirm this assessment is precisely the direct effect of *ISCC*: both patents were granted by the UKIPO in October 2015[38], and the EPO published new Guidelines including indirectly this new perspective[39]. From now on, the field of hESC is relatively open to the protection granted by patents and, in consequence, to the interplay between intellectual property rights and competition. This interplay in the field of human stem cell research is the topic of the following section.

PART II: THE INTERPLAY BETWEEN COMPETITION AND INTELLECTUAL PROPERTY

Chapter 1. Patent Rights and Competition law: a head-on clash?

1. General overview and possible conflictive scenarios

After the ruling of the ECJ in *ISCC*, inventions related to hESC's research can now be protected under the "protective umbrella"[40] of the European patent system. Actually, as it has been indicated above, the UKIPO has granted two patents concerning the process

[36] *Ibid.,* paragraph 26.
[37] For a deep analysis of these questions see NORDBERG and MINSSEN, *supra* note 13, pages 9-22.
[38] UK Patent GB2431411 "Parthenogenic activation of human oocytes for the production of human embryonic stem cells", and UK Patent GB2440333 "Synthetic cornea from retinal stem cells derived from human parthenotes", both granted 06 October 2015 and Published in the Patents and Designs Journal on 04 November 2015.
[39] Guidelines for Examination in the European Patent Office (November 2015), Part G, Chapters II-5.3 to to III on R 28 (c).
[40] C.T.TAYLOR, A. SILBERSTON and Z.A. SILBERSTON, *The Economic Impact of the Patent System: A Study of the British Experience*, London, Oxford University Press, 1973, p. 212.

for obtaining hESC using parthenotes and synthetic corneas derived from it. However, for the purposes of this thesis, it is not still evident why patents should be analysed from a competition law perspective.

In economic terms, patents use to be described as a legal monopoly which enables the holder of a patent to exclude or to block the use of the invention to third parties for a certain period of time[41]. From a competition law perspective, articles 101 and 102 of the Treaty on Functioning of the European Union (hereinafter, TFEU) could be applied to such a situation. In fact, this was the problem confronted by the ECJ *Parke Davis*[42], a landmark case in the relationships between IP and competition. Here, the ECJ had to determine if "the concept of practices prohibited under articles 85(1) and 86, possibly considered with articles 36 and 222 of the Treaty, includes the action of the holder of a patent issued in a member state when, by virtue of that patent, he requests the national courts to prevent all commercial dealing in the territory of that state in a product coming from another member state which does not grant an exclusive right to manufacture and sell that product"[43].

In *Parke Davis*, the ECJ established the famous distinction between "existence" and "exercise" with this wording: "the existence of the rights granted by a member state to the holder of a patent is not affected by the prohibitions contained in articles 85(1) TFEU and 86 of the Treaty; secondly, that the exercise of such rights cannot of itself fall either under article 85(1) TFEU, in the absence of any agreement, decision or concerted practice prohibited by that provision, or under article 86, in the absence of any abuse of a dominant position"[44]. This also means, as it has been correctly pointed out by the doctrine, that a patent does not "automatically confer market power"[45] and

[41] D. KAESMACHER and T. STAMOS, *Brevets, marques, droits d'auteur…mode d'emploi,* Liege, Edi.Pro, 2009, p. 73.
[42] Judgment in *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm*, C-24/67, ECLI:EU:C:1968:11.
[43] *Ibid.*, p. 71.
[44] *Ibid.*, p. 72. For a critic concerning the artifical división between right and exercise, see J-S. BERGÉ, *La protection internationale et communautaire du droit d'auteur: essai d'une analyse conflictuelle*, Paris, Libraire générale de droit et de jurisprudence, 1996, p. 127.
[45] A. BAKARDJIEVA ENGELBREKT, "Stem cells patenting and competition law", in A. PLOMER and P. TORREMANS, *Embryonic stem cell patents: European Law and Ethics,* New York, Oxford University Press, 2009, p. 371.

thus the use of a patent can only be considered under article 102 TFEU if the patent holder is in a dominant position according to the general theory of competition law. This thesis will be focused, due to limitations of space, only in the application of article 102 TFEU and refusals to license.

But, what would be in practice the potential anticompetitive scenarios? In general terms, two main possibilities can be identified[46] for the purpose of this research. The first scenario[47] consists on a patent, protecting an invention which cannot be substituted, held by one undertaking (A). A does not have activities in the downstream market for this invention and it its activities are related only to the upstream market. The second undertaking (B) asks for an authorization to use the patent in the downstream market. If A refuses to give a license, B will not able to access or to stay in that downstream market.

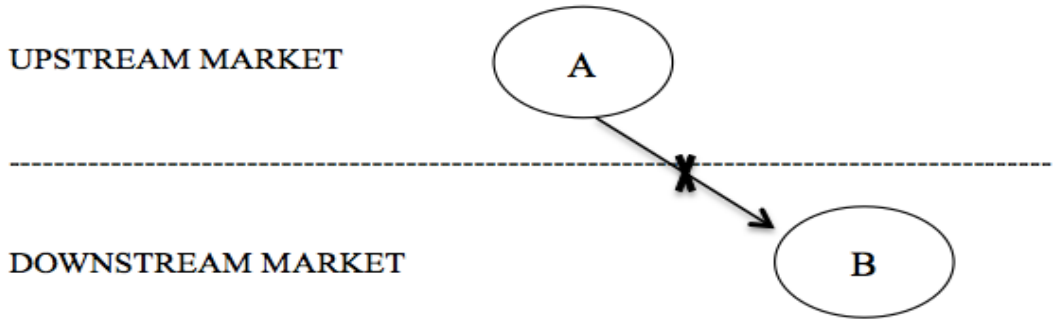

*Figure 1

In the second scenario, A also carries out activities in the downstream market. Here, B will be excluded again from the downstream market if A refuses to give a license. In terms of competition, as it will be indicated in the next sections, the situation differs from the first one because A is using its dominant position in the upstream market to extend its power to the secondary market[48]. This idea is known is competition law as the

[46] E. TEONG SEE, "Revisiting Anticommons and Blockings in the Biotechnology Industry", (2008) 11 (3) *The Journal of World Intellectual Property*, pages 148-151.
[47] *Ibid.*, p. 148.
[48] See Judgment in *Consorzio italiano della componentistica di ricambio per autoveicoli and Maxicar v Régie nationale des usines Renault*, C-53/87, ECLI:EU:C:1988:472.

"leverage theory", which explains that, by refusing to license, the monopolists seek to extend their monopoly power to a downstream-related market[49].

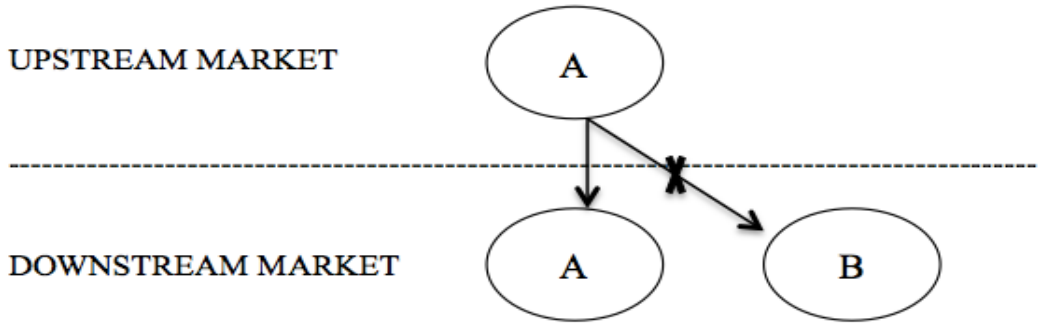

*Figure 2

In this line, the exercise of an IPR will never be considered under article 102 TFEU if the holder (A) is not dominant in the relevant market[50]. However, what should the answer be when the holder has such a dominant position? Or, in the case of this research, what would be the result of the exercise of an IPR by ISCC[51]?

The response involves the analysis of important legal aspects. A simple "no, the right would be ineffective if it cannot be exercised" or "yes, it is an abuse of dominant position" does not take into account the delicate balance between competition law and intellectual property rights. Different positions in the doctrine try to find this "balance between the interests of distributors, artists, inventors and creators and the interests of consumers"[52] giving more weight to one element or the other.

JACOB, defender of the role of IPR in the protection of innovation, gives a very illustrative explanation of this problem. The point of departure is that IPR, as exceptions to free competition, provide advantages to society that outweigh the advantages of the

[49] For a classical analysis of the leverage theory, see L. KAPLOW, "Extension of Monopoly Power Through Leverage", (1985) 85 *Columbia Law Review*, pages 515-556.
[50] The question of the relevant market in hSCs research will be analysed in the third part of this thesis.
[51] The question of the possible dominant position of this actor will be analysed in the third part of this thesis.
[52] Margrethe Vestager, Opening of the *19th IBA Competition Conference*, Florence, 11 September 2015. Available on: https://ec.europa.eu/commission/2014-2019/vestager/announcements/intellectual-property-and-competition_en

later[53]. The monopoly is accepted as retribution to the investment made by inventors, who disclose in a patent the information about the invention and thus contribute to expansion of knowledge, technical development and creation of new competitive markets previously inexistent[54].

In any case, for the previous author, the very essence of patent rights is connected to the defence of competition[55]. In this line, the *rationale* of the requirement of novelty would be to avoid holders to monopolise an area where competition should be free[56]. Also, the time limit is a measure to avoid this suspension of free competition for an excessive period of time[57]. The principle here would be that "you get a monopoly but is a monopoly in something which would not have existed (or existed as soon) but for your inventive contribution. The law interferes not with ordinary competition, but with competition in something which would not have existed but for the inventor"[58].

On the other hand, some authors have adopted a different approach considering that the proliferation of IPR[59] or the refusal to license is harmful for innovation[60], especially in follow-on innovation markets where the main activity is research and product markets where undertakings asking for a license would like to introduce a new or improved product[61]. From this perspective, public intervention would be necessary to avoid obstructions in the way of innovation[62].

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[53] R. JACOB, "Competition Authorities Support Grasshopers: Competition Law as a Threat to Innovation", (2013) 9 (2) *Competition Policy International*, p. 15.
[54] L. LEBLOND, *Pratiques anticoncurrentielles et brevets: Étude en faveur de la promotion européenne de l'innovation*, Bruxelles, Bruyant, 2014, pages 10-15.
[55] JACOB, *supra* note 53, p. 15.
[56] *Ibid*.
[57] *Ibid*.
[58] *Ibid*.
[59] For a deep analysis of this topic, see M.A. HELLER and R.S. EISENBERG, "Can Patents Deter Innovation? Anticommons in Biomedical Research", (1998) 280 Science, pages 698-601; M. SIRAGUSA, "The EU Pharmaceutical Sector Inquiry: New Forms of Abuse and Article 102 TFEU" in G. CAGGIANO, G. MUSCULO and M. TAVASSI (eds.), *Competition Law and Intellectual Property: a European Perspective*, Alphen anns den Rijn, Kluwer Law International, 2012, pages 177-189 and E. MELON, "Patents, Competition Law and Open Innovation: A Study of Global Patent Warming", (supervision of Prof. M. SIRAGUSA), Bruges, 2012.
[60] T. KÄSEBERG, *Intellectual Property, Antitrust and Cumulative Innovation in the EU and the US*, Oxford, Hart Publishing, 2012, p.5.
[61] *Ibid.*
[62] TEONG SEE, *supra* note 46, p. 149.

What has been the answer in the EU legal order to this problem? The following chapter will analyse the case law of the ECJ concerning the interplay between competition law and patent law in cases of refusal to license. After this theoretical background, in which the case law is far from being clear, this thesis will attempt to evaluate its application and effects on the market of hSC. The results will allow to determine if the balance is in favour of the interests of the holders, in a point of equilibrium or "favouring grasshoppers, positively helping them sing in the summer (I.e. gathering profits now) and saying: do not worry, sing away, when winter comes we will make the ants feed you"[63], paying better "to be a copyist than an innovator"[64].

Chapter 2. Intellectual Property Rights and refusals to license: has the ECJ to catch up to science?

The two conflictive scenarios presented above raise one of the most conflictive questions analysed by the ECJ in this field: the existence or not of situations when "the protective shield of exclusivity can be cracked open by means of competition law in order to ensure access to the protected IP right"[65]. The analysis is delicate because, as correctly pointed out by Advocate General (hereinafter, AG) JACOBS in reference to compulsory licensing: "the right to choose one's trading partners and freely to dispose on one's property are generally recognised principles in the law of the Member States"[66] and that "incursions on those rights require careful justification"[67].

The first answer to this question was elaborated in the United States and later on reproduced by the European case law. The Supreme Court introduced in *Terminal Railroad Combination* some exceptional circumstances under which an undertaking could be compelled to give access to a vital source to other competitors[68]. Although this

[63] JACOB, *supra* note 53, p. 15.
[64] *Ibid*.
[65] BAKARDJIEVA ENGELBREKT, *supra* note 45, p. 373.
[66] Opinion of AG Jacobs in Case C-7/97, *Oscar Bronner GmbH & Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG, Mediaprint Zeitunsvertriebsgesellschaft mbH & Co. KG and Mediaprint Anzeigengesellschaft mbH & Co. KG.,* delivered on 26 November 2008, paragraph 56.
[67] *Ibid*.
[68] For a classic review of this judgment under U.S. law, see P. AREEDA, "Essential Facilities: An Epithet in Need of Limiting Principles", (1989) 58 *Antitrust Law Journal*, pages 841-853.

application of competition law, named by scholars as the "essentials facilities doctrine", was not related to products protected by IP rights, the similarities between supply of vital tangible properties and license to non-substitutable products protected by IP rights have inspired the EU case law[69]. The point of departure of the case law about "essential facilities" within the EU is *Commercial Solvents*[70].

1. Commercial Solvents

In the 60s and 70s, Commercial Solvents acted in the EEC as the only producer and seller of raw materials used for the manufacture of ethambutol, used as an anti-tuberculosis drug[71]. Since 1966, Commercial Solvents had supplied raw materials to Zoja, a manufacturer of ethambutol. However, after a period during which Zoja had suspended the contractual relationship, Commercial Solvents refused to continue supplying Zoja and decided to start activities in the downstream market of ethambutol[72] (this would be an example of the second scenario explained above).

The EC, after a complaint of Zoja about this situation, decided that this refusal to supply was an abuse of dominant position[73]. This decision was confirmed in appeal by the EC saying that "an undertaking which has a dominant position in the market in raw materials and with the object of reserving such raw as materials for manufacturing its own derivatives, refuses to supply a customer, which is itself a manufacturer of these derivatives, and therefore risks eliminating all competition on the part of this customers, is abusing its dominant position"[74].

In this pioneer judgment, the ECJ based its reasoning in the monopoly of Commercial Solvents due to the lack of alternative raw materials. Rejecting the argument of

[69] For a deep analysis of the similarities between them including Decisions of the European Commission, see J. TEMPLE LANG, "Defining Legitimate Competition: Companies' Duties to Supply Competitors and Access to Essential Facilites", (1994) 18 (2) *Fordham International Law Journal*, pages 439-523.
[70] Judgment in *Istituto Chemioterapico Italiano S.p.A. and Commercial Solvents Corporation v Commission of the European Communities*, joined cases C-6/73 and C-7/73, ECLI:EU:C:1974:18.
[71] *Ibid.*, paragraph 19.
[72] *Ibid.,* paragraph 7.
[73] *Ibid.*, paragraph 21.
[74] *Ibid.,* paragraph 25.

Commercial Solvents that the development of alternatives methods would not entail excessive costs, the ECJ considered that "in the present conditions of economic competition it is not possible to have a recourse on an industrial scale to methods of manufacture of ethambutol based of the use of different raw materials"[75] because the alternatives methods were experimental and were not developed enough to cover industrial needs[76]. Despite of the antiquity of this judgment, such reasoning could have an important impact on the field of hSC, as this research will analyse in following chapters.

2. Volvo v. Veng

In this case, the ECJ was confronted for the first time with the question of refusal to license IPR. It's also the first example in the case law of equal treatment between refusals to supply and refusals to grant licenses[77]. Again in the second scenario, Volvo refused to supply to Veng vehicles' spare parts protected by a design. The general position adopted here is initially protectionist of IP rights:

> "The right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right. It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design *would lead to the proprietor thereof being deprived of the substance of his exclusive right*, and that a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position"[78].

However, the ECJ added some circumstances under which the refusal to supply can be considered an infringement under article 102 TFEU: "the arbitrary refusal to supply

[75] *Ibid.*, paragraph 16.
[76] *Ibid.*, paragraph 13.
[77] With similar facts and same outcome of the ECJ, see the Judgment in *Régie nationale des usines Renault SA v Maxicar SpA and Orazio Formento*, C-38/98, ECLI:EU:C:2000:225.
[78] Judgment in *AB Volvo v Erik Veng (UK) Ltd*, C-238/87, ECLI:EU:C:1988:477, paragraph 8.

spare parts to independent repairers, the fixing of prices for spare parts at an unfair level or a decision no longer to produce spare parts for a particular model even though many cars of that model are still in circulation, provided that such conduct is liable to affect trade between Member States"[79]. The rationale of the ECJ seems to be that even if the exercise of the right does not constitute an abuse itself, such exercise can be abusive if it is the tool to adopt further anticompetitive conducts as the extension of the dominant position to other markets or the charge of excessive prices[80].

The consequence of *Volvo* is that, in very exceptional circumstances, when the dominant undertaking uses the IPR as a vehicle to exclude competition on secondary markets, the authorities of competition can order under article 102 TFEU a compulsory supply or a reduction of prices of products protected by IP[81]. The impact of this judgment, which is an application of the reasoning *in Commercial Solvents* into the field of IP, will be extended with the landmark case of *Magill*[82].

3. Magill

The situation in *Magill*[83] is a good picture to illustrate that an IP right does not give automatically dominance in the market unless there are other circumstances such as the lack of substitutive products, *de facto* standards, etc[84]. On the one hand, ITV, RTE and BBC held under UK and Irish law a copyright over the lists of programmes they were broadcasting, publishing a guide with their own programmes every week[85]. They were also giving free license to newspapers with their daily listings of programmes[86].

On the other hand, Magill had the idea of a weekly guide including programs of all TV

[79] *Ibid.*, paragraph 9.
[80] See the judgment in *Commercial Solvents* ECLI:EU:C:1974:18.
[81] S.D. ANDERMAN and H. SCHMIDT, "EC competition policy and IPRs", in S.D. ANDERMAN, *The Interface between Intellectual Property Rights and Competition Policy*, Cambridge, Cambridge University Press, 2007, p. 56.
[82] *Ibid.*
[83] Judgment in *Radio Telefis Eireann (RTE) and Independent Television Publications Ltd (ITP) v Commission of the European Communities*, hereinafter *Magill,* joined cases C-241/91 and C-242/91, ECLI:EU:C:1995:98.
[84] BAKARDJIEVA ENGELBREKT, *supra* note 45, p. 378.
[85] Judgment in *Magill,* ECLI:EU:C:1995:98, paragraphs 6 and 8.
[86] *Ibid.*, paragraph 9.

channels, product which was not existent in the market at that time[87]. However, the broadcasting companies decided to refuse the license requested by Magill. For this reason, Magill complained to the EC considering that such a denial would fall under article 102 TFEU. In effect, the EC confirmed that broadcasters had abuse of their individual dominant position in relation to their own listings and order them to supply such information[88]. This approach was confirmed by subsequent appeals before the Court of First Instance[89] (now General Court, hereinafter GC) and the ECJ.

The ECJ considered in this case that all broadcasters had a "de facto monopoly over the information used to compile listings for the television programmes received in most households in Ireland and 30% to 40% of households in Northern Ireland"[90]. The particular abusive resulted, according to the ECJ, from the fact that the refusal prevented the emergence of a new product with potential consumer demand, namely these comprehensive guides[91]. Specifically, the infringement would be that "the appellants, by their conduct, reserved to themselves the secondary market of weekly television guides by excluding all competition on that market"[92].

Therefore, *Magill* gives more clarity in relation to the possibility of using competition law in order to control the exercise of IPR. This advance can be especially observed in the summary of the judgment: "The conduct of an undertaking in a dominant position, consisting of the exercise of a right classified by national law as 'copyright', cannot, by virtue of that fact alone, be exempt from review in relation to Article 86 of the Treaty". One can distinguished some relevant elements in this judgement[93]:

- No actual or potential substitute for the protected product which is the raw in the secondary market[94].

[87] *Ibid.*, paragraph 10.
[88] *Ibid.*, paragraph 12.
[89] Judgment of 10 July1991 *Radio Telefis Eireann v Commission of the European Communities*, T-69/89, ECLI:EU:T:1991:39.
[90] Judgment in *Magill,* ECLI:EU:C:1995:98, paragraph 47.
[91] *Ibid.*, paragraph 56.Some author considers the concept of "new product" as an "objet juridique non identifié", see G. DEZOBRY, *La théorie des facilités essentielles: Essentialité et Droit Communautaire de la Concurrence*, Paris, Libraire générale de droit et de jurisprudence, 2009, pages 320-323.
[92] Judgment in *Magill,* ECLI:EU:C:1995:98, paragraph 47.
[93] BAKARDJIEVA ENGELBREKT, *supra* note 45, p. 379.
[94] Judgment in *Magill,* ECLI:EU:C:1995:98, paragraph 52.

- The refusal to license prevents the appearance of a new product with potential consumer demand not offered by the IP holder[95].
- No objective justification for the refusal[96].
- The holder reserves to himself the secondary market[97].

However, the previous elements contained in the judgment also casted some shadows in relation to their exact meaning or if they were cumulative or not. Is really this weekly guide a new product in comparison to the previous ones[98]? Could holders of IPR avoid the requirement of the prevention of appearance of a product by offering the product themselves[99]? Some have pointed out that this judgment should be considered as a way of limiting a highly questionable intellectual property right in an exceptional situation[100].

In the same line, RIDYARD describes clearly the possible reason for the approach of the ECJ in *Magill* with the following words: "enforcing compulsory licensing for TV listings […] does nothing to upset dynamic incentives because the incentive to produce and disseminate TV listings will be the same irrespective of whether the broadcasters are protected from competition in the TV guides market"[101]. The importance of these discussions about the scope of *Magill*, however, would be reduced after the judgment in *Bronner*[102], which is going to be commented in the next section.

[95] *Ibid.,* paragraph 54.
[96] *Ibid.*, paragraph 55.
[97] *Ibid.*, paragraph 56.
[98] S.J. EVRARD, "Essential Facilites in the European Union: *Bronner* and Beyond", (2004) 10 *Columbia Journal of European Law*, p. 12.
[99] E. DERCLAYE, "Abuses of Dominant Position and Intellectual Property Rights: A Suggestion to Reconcile the Community Courts Case Law", (2003) 26 *World Competition*, pages 685-705.
[100] V. KORAH, "The Interface between Intellectual Property and Antitrust: The European Experience", (2002) 69 (3) *Antitrust Law Journal*, p. 810.
[101] D. RIDYARD, "Essential Facilites and the Obligation to Supply Competitors under UK and EC Competition Law", (1996) 17 (17) *European Competition Law Review*, p. 446.
[102] Judgment in *Oscar Bronner GmbH & Co. KG v Mediaprint Zeitungs- und Zeitschriftenverlag GmbH & Co. KG, Mediaprint Zeitungsvertriebsgesellschaft mbH & Co. KG and Mediaprin Anzeigengesellschaft mbH & Co. KG.*, hereinafter *Bronner*, C-7/97, ECLI:EU:C:1998:569.

4. Bronner

Although *Bronner* does not involve IP protected products, it is relevant for this topic because, in the similar framework of refusals to supply[103], gives a new perspective of the definition of "essential facility" or "indispensability". Mediaprint, the dominant publisher of newspapers in Austria, created an "early bird" system of distribution of newspapers[104] and refused the access to one of its competitors, Oscar Bronner. In proceeding before the national court, a preliminary question was referred to the ECJ about the possible abuse of dominant position of Mediaprint[105].

After considering that it was up to the national courts to determine what is the relevant market and whether Mediaprint was dominant of not, the ECJ held that, in order to be considered as an abuse of dominant position, it is necessary[106]:

- Not only that the refusal was likely to eliminate all competition in the market from the perspective of the person requesting the service of home delivery.
- But also that the refusal cannot be objectively justified.
- Inasmuch as there is no actual or potential substitute in existence for that home-delivery scheme.

While the first and second conditions were already existent in the case law previously analysed, the new element of this judgment comes with the description of "actual or potential substitute". The ECJ, following the Opinion of AG JACOBS[107], considered three aspects:

- First, that there were another systems of distribution (such as shops and kiosks) even thought they might be less advantageous for the distribution of certain

[103] This similarity is analysed in the second part of this thesis, page 29.
[104] Judgement in *Bronner*, ECLI:EU:C:1998:569, paragraph 7.
[105] *Ibid.*, paragraph 11.
[106] *Ibid.*, paragraph 41.
[107] Opinion of AG Jacobs in *Bronner*, *supra* note 66, paragraph 68.

newspapers[108].

- Second, that there were no "technical, legal or even economic obstacles capable of making it impossible, or even unreasonably difficult, for any other publisher of daily newspapers to establish, alone or in cooperation with other publishers, its own nationwide home-delivery scheme and use it to distribute its own daily newspapers"[109].
- In third place, that it was not sufficient that the establishment of a second system was not economically viable because of the small circulation of the newspaper of Bronner. Contrary, it should be demonstrated that was not economically possible to create a system with a circulation comparable to Mediaprint.

Two are the relevant results of this judgment for this thesis. First, the establishment of high standards at the time of considering a product as "indispensable", taking into account the competitive conditions in the downstream market[110]. Secondly, the disappearance of the "new product condition"[111], although this phenomenon will be clarified with the case analysed in the following lines.

5. IMS Health

In *IMS Health*[112], the ECJ faced a similar situation to the previous one but with the presence of a product protected by IP rights. IMS Health provides reports to the pharmaceutical sector. These reports are based on the data recollected from the own pharmacies and divided according to a structure of bricks[113], representing each one of them a different geographical area. Such system, protected by copyright, has been subsequently improved thanks to the participation of the own clients, the members of the pharmaceutical industry[114].

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[108] Judgment in *Bronner,* ECLI:EU:C:1998:569, paragraph 44.
[109] *Ibid.,* paragraph 45.
[110] EVRARD, *supra* note 98, p. 18.
[111] For a deep analysis of a possible difference between refusals to supply and to license IP, see DERCLAYE, *supra* note 99.
[112] Judgment in *IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG.*, C-418/01, ECLI:EU:C:2004:257.
[113] *Ibid.,* paragraph 4.
[114] *Ibid.*, paragraph 5.

A competitor, NDC Health, was using a system derivate from the one of IMS Health to provide the same type of reports[115]. IMS Health, arguing a violation of copyright, brought an action before the national courts[116]. In a parallel procedure initiated by NDC Health, the EC ordered IMS health to grant a license to use to all the undertakings present on the market for the provision of German regional sales data[117].

On the one hand, IMS Health brought an action for annulment against the Decision of the EC. On the other, the national court decided to refer a preliminary question about the possible anticompetitive use of the right to obtain an injunction. The ECJ was therefore in front of two proceedings looking for the same answer. Following a narrow approach not very different from *Bronner*, the ECJ clarified the following points which will be very useful for the following chapters of this thesis:

i. The holder of IPR must be dominant in the upstream market and the IP right must give access to a product indispensable (with the definition in *Bronner*) for a particular business[118].
ii. There must be two markets, an upstream and a downstream market[119].
iii. Prevention of the emergence of a new product with potential consumer demand, which cannot be a duplication of the goods already offered by the IP holder. Therefore, it must be a good not offered by the owner of the right and for which there is a potential consumer demand[120].
iv. No objective justification[121].
v. Exclusion of all competition in the secondary market[122].

The third element, namely the prevention of a product that the IP holder does not offer himself, was highly criticized by the doctrine. This seems to diverge from the approach adopted for the refusals to supply in *Commercial Solvents*. The reason for this

[115] *Ibid.*, paragraph 7.
[116] *Ibid.*, paragraph 9.
[117] *Ibid.*, paragraph 12.
[118] *Ibid.*, paragraphs 41-44.
[119] *Ibid.*, paragraph 45.
[120] *Ibid.*, paragraph 48.
[121] *Ibid.*, paragraph 51.
[122] *Ibid.*, paragraph 52.

difference is exposed by AG TIZZIANO: "I consider that the refusal to grant a licence may be deemed abusive only if the requesting undertaking does not wish to limit itself essentially to duplicating the goods or services already offered on the secondary market by the owner of the intellectual property right but intends to produce goods or services of a different nature which, although in competition with those of the owner of the right, answer specific consumer requirements not satisfied by existing goods or services"[123].

This reasoning is highly condemned by HEINEMANN who considers that tangible and intangible property should be protected in the same way[124]. The inconsistent reasoning of the ECJ would be, according to this author, the use of *Magill* as a leading case[125]. The typical context is not a secondary market left completely unexploited, but a reserve of the IP holder for himself in order to exploit it[126]. Excluding this last situation from the control of competition law would be an excessive concession to IPR[127]. The next and last step of the ECJ closes temporarily the case law about the "essential facilities" allowing to examine it in the field of hSC is *Microsoft*[128].

6. Microsoft

In *Magill* and *IMS Health* the ECJ established the possibility of compulsory licensing in exceptional circumstances, specifically where the undertaking that seeks for a license intends to produce a new product for which there is potential consumer demand. In *Microsoft,* the EC held that Microsoft had dominance in two markets: PC operative

[123] Opinion of AG Tizziano in *IMS Health IMS Health GmbH & Co. OHG v NDC Health GmbH & Co. KG.*, delivered on 2 October 2003, paragraph 62.
[124] A. HEINEMANN, "Compulsory Licences and Product Integration in European Competition Law – Assessment of the European Commission's Microsoft Decision", (2005) 36 *International Review of Intellectual Property and Competition Law*, p. 71.
[125] *Ibid*.
[126] *Ibid.*, p. 72.
[127] *Ibid.,* p. 71.
[128] Judgment of 17 September 2007, Microsoft *Corp. v Commission of the European Communities*,T-201/04, ECLI:EU:T:2007:289. For different analysis of this judgment, see J.-Y. ART, "Comment Microsoft a change", (2008) 17 *Revue Lamy de la Concurrence*, pages 173-175; E. TREPPOZ "Aux confins du droit de la concurrence et du droit de la propriété intellectuelle: l'affaire Microsoft", (2008) 17 *Revue Lamy de la Concurrence,* pages 163-167; and J.-Y. DE CARA, "L'affaire Microsoft, une mise à l'épreuve du droit antitrust", (2008) 17 *Revue Lamy de la Concurrence*, pages 132-136.

systems and work group server operating systems[129]. The EC also considered that the refusal to supply competitors with the interoperability information necessary to develop products in the market of servers was an abuse of dominant position. In order to avoid the payment of the fine imposed, Microsoft brought an action for annulment against this decision before the GC. In this long-waited decision, the GC analysed the cases of *Magill*, *Bronner* and *IMS Health* and reached the following conclusions in relation to the "exceptional circumstances" around which the refusal to license by a dominant undertaking can constitute an abuse:

> "It also follows from that case-law that the following circumstances, in particular, must be considered to be exceptional:
>
> - In the first place, the refusal relates to a product or service indispensable to the exercise of a particular activity on a neighbouring market;
> - In the second place, the refusal is of such a kind as to exclude any effective competition on that neighbouring market;
> - In the third place, the refusal prevents the appearance of a new product for which there is potential consumer demand.
>
> Once it is established that such circumstances are present, the refusal by the holder of a dominant position to grant a licence may infringe Article 82 EC unless the refusal is objectively justified. The Court notes that the circumstance that the refusal prevents the appearance of a new product for which there is potential consumer demand is found only in the case-law on the exercise of an intellectual property right"[130].

The first innovation of this judgement is the new wording of the criteria of "excludes any effective competition" instead of "all competition". Taking into account that the elimination of all competition is difficult and it would limit substantially the scope of application of article 102 TFEU, the GC says that it is not necessary for the EC to

[129] Commission Decision of 24 May 2004 relating to a proceeding pursuant to Article 82 of the EC Treaty and Article 54 of the EEA Agreement against Microsoft Corporation, [2004], O.J. 32/23, at 17.
[130] Judgment in *Microsoft Corp. v Commission of the European Communities*, T-201/04, ECLI:EU:T:2007:289, paragraphs 332-332.

demonstrate that "all competition in the market would be eliminated: it was sufficient to show that the refusal to supply is liable, or likely, to eliminate all effective competition"[131].

The second new element provided by *Microsoft* concerns precisely the conflictive "new product requirement". Here, the GC clearly establishes that "the circumstance relating to the appearance of a new product, as envisaged in *Magill* and *IMS Health*, paragraph 107 above, cannot be the only parameter which determines whether a refusal to license an IPR is capable of causing prejudice to consumers within the meaning of Article 82(b) EC"[132]. In consequence, the ECJ stated that the EC that was not manifestly incorrect when it introduced a new interpretation of the new product criteria: the restriction of technical development[133].

The consequences of this new statement, i.e. that a restriction of technical development may suffice to establish an infraction of article 102 TFEU, are not clear and will require further development by the case law[134]. However, as it will be analysed in the relevant section, the impact of this judgment in the area of biotechnology and hSC can be especially important due to the high technical development of this area based on primary sources, protected in many occasions by IP rights.

7. Compilation of the case law: the Commission's Guidance on article 102 Enforcement Priorities

In paragraphs 75 to 90, the EC builds the *Commission Communication*[135] on the previous case law of the ECJ and the GC without any distinction between refusals to supply and refusals to grant a license. The EC specifically says that "the concept of

[131] *Ibid.,* paragraph 563.
[132] *Ibid.,* paragraph 647.
[133] *Ibid.*
[134] R. WHISH and D. BAILEY, *Competition Law,* Oxford, Oxford University Press, 2015, p. 845.
[135] Commission Communication, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance), 2009/C 45/02 (24.02.2009). The purpose of this document is not to constitute a statement of the law put the priorities of enforcement of the EC in exclusionary abuses. This Guidance does not apply to exploitative abuses.

refusal to supply covers a broad range of practices, such as a refusal to supply products to existing or new customers, refusal to license intellectual property rights, including when the licence is necessary to provide interface information, or refusal to grant access to an essential facility or a network"[136].

In this sense, the EC considers that a refusal will be an enforcement priority if:

- The refusal relates to a product or service that is objectively necessary to be able to compete effectively on a downstream market;
- The refusal is likely to lead to the elimination on the downstream market; and
- The refusal is likely to lead consumer harm.

The Guidance refers in order to interpret these requirements to the case law analysed above. Specifically, the criteria of "consumer harm" is related to Microsoft: "new or improved goods or services for which there is a potential consumer demand or is likely to contribute to technical development"[137]. These steps established by the EC and the case law related to it, as explained above, will guide the analysis of the possible application of the essential facilities doctrine to the market of hSC.

PART III: HUMAN STEM CELLS, PATENTS RIGHTS AND COMPETITION LAW

The previous section has analysed how the controller of a vital input can use patent rights to deny access to a product which is vital to compete, and how the EU case law has developed the possibility of compelling the dominant holder in the upstream market to provide access to this input in the downstream market. At the beginning of this thesis, it has been explained how the restrictions to patentability has been reduced in the field of hSC with the judgment in *ISCC*, and how it has enable to grant patents over

[136] *Ibid.,* paragraph 78.
[137] *Ibid.,* paragraph 87.

parthenogenesis methods in UK. In the remaining part of this document, it will be analysed how patents can create problems in this new market and how the previous case law can be used as a competition tool in order to solve them.

Taking into account that both the market and the judgment of the ECJ opening it are young, there is not any case yet concerning this specific topic. In this sense, the present contribution will serve as a possible source for potential problems in a sector whose potential of development is very high[138], as well as its impact in the welfare of the society. In order to achieve this objective, the next sections will analyse the application of the elements of the essentials facilities doctrine in the field of human stem cell research.

The hypothesis analysed is the following: ISCC has invented a method to transform adult stem cells into pluripotent cells (parthenogenesis). The result is a cell with all the virtues of an embryonic cell but outside of the "morality exception" clause to patentability thanks to the judgment of the ECJ. ISCC is granted two patents in UK: one the method of parthenogenesis and one of its results, namely synthetic corneas used in several ophthalmological therapies. ISCC refuses to give licenses to other undertakings over these patents.

Why would ISCC refuse to give a license? The answer given by DAVIS is clear: from now on, ISCC is the only undertaking with access to use and have patents over groundbreaking cures based on parthenotes[139]. Even if at the beginning ISCC would lose millions of euros in royalties by refusing licenses, the profits once you find a cure

[138] In this sense, one of the best indicators of an emerging area is the growth of research in the field. Between 2008 and 2012, stem cells publications show an annual growth of 7% in comparison to the world average rate of 2,9% in all other disciplines including several European countries (especially Italy, the Netherlands, Sweden, UK, France, Denmark and Austria). See ELSEVIER, EUROSTEMCELL and ICEMS: "Stem Cell Research: Trends and Perspectives on the Evolving International Landscape", (2013) *Report*, available at:
http://www.eurostemcell.org/files/Stem-Cell-Report-Trends-and-Perspectives-on-the-Evolving-International-Landscape_Dec2013.pdf (Last Accessed 21 April 2016).

[139] A.R. DAVIS, "Patented Embryonic Stem Cells; "The Quintessential Essential" Facility?", (2005) 205 *Georgetown Law Journal*, pages 2-3. The author examines a similar situation in US which is not hypothetical: the patent 806 for the preparation of human embryonic stem cells.

would be of billions[140]. While a small centre of research would not have interest in refusing the license (Figure 1), a big company with presence in both the upstream and the downstream market can see the researchers in this last market as potential competitors to find the therapy (Figure 2)[141].

Chapter 1. Application of the essential facilities test to the field of human stem cell research.

1. The patent controlled by a dominant undertaking is necessary to be able to compete effectively on a downstream market.

The first requirement contains two elements: the "objective necessity of the input"[142] and the dominant position of the undertaking. In order to analyse this first element the EC, following *Microsoft*, reminds that it is not necessary that the competitor would not enter or stay on the downstream market. It is therefore necessary, following *Bronner*, that the competitors cannot effectively create alternative sources capable of allowing competitors to exert a competitive constraint on the dominant undertaking in the downstream market.

Taking into account that hESC are highly constrained because of morality questions and the research based on adult cells has very limited potential, it is difficult or even impossible to compete in the downstream market on human stem cell therapies without access to parthenotes[143]. And, in this specific case, no other undertaking holds even the minimal share of the market to produce or license parthenotes. ISCC is the only undertaking that can provide or give licenses of parthenotes to the researchers in the downstream market holding, therefore, a dominant position in the upstream market of human stem cells.

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[140] *Ibid.*
[141] *Ibid.*
[142] Commission Communication, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance), 2009/C 45/02 (24.02.2009), paragraph 83.
[143] The statistics show a notable decrease of activity in human embryonic stem cell and increased activity in induced pluripotent stem cells. See ELSEVIER, *supra* note 138, p. 6.

2. The refusal is likely to lead to the elimination on the downstream market

In this point the EC apparently unifies the first and the second requirements: "if the requirements set out in paragraphs 83 and 84 are fulfilled, the Commission considers that a dominant undertaking's refusal to supply is generally liable to eliminate, immediately or over time, effective competition in the downstream market"[144].

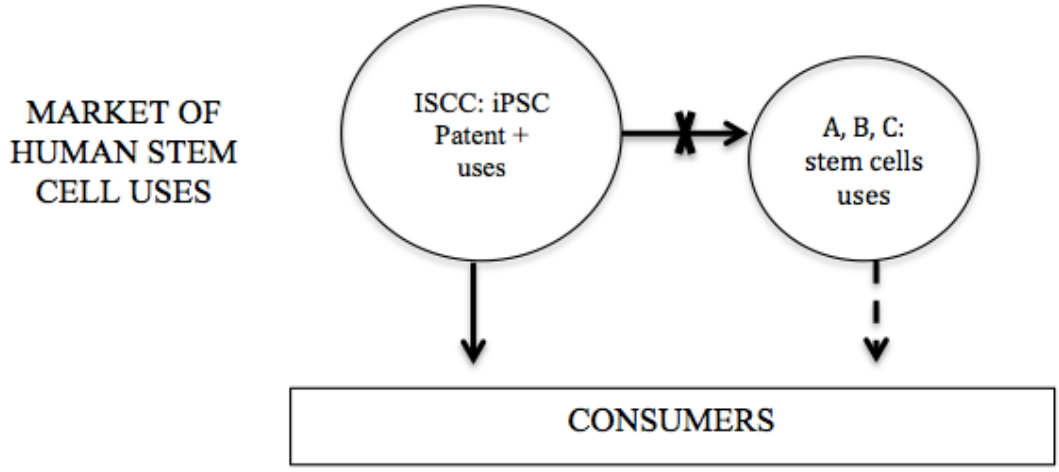
The link between these two elements seems to be in line with the new criteria of "effective competition" established in *Microsoft*: the likelihood of eliminating competition is generally greater the higher the degree of indispensability[145]. This wording could be a reaction to the correct criticism of some author who considered that there was no difference between these two conditions: "if a facility is essential for the requesting undertaking, it will inevitably prevent that undertaking from competing on the market and, thus, will eliminate it. Alternatively, if the refusal to use the facility is not likely to eliminate all competition of the part of the requesting undertaking, it inevitably means that the facility is not essential"[146].

In any case, there is still the necessity to define what are in this context the upstream and the downstream market. One can argue that two markets could be distinguished: an upstream market for the production of human stem cells (iPSC, hESC and adult stem cells) and a downstream market which incorporates these stem cells (principally stem cell therapies, drug testing and organ transplants)[147].

It would be reasonably to oppose this separation of markets as incorrect as there is only one market for stem cell uses (Figure 3). Here, iPSC would be only one input that gives competitive advantage to ISCC thanks to the royalties that can be received for the licenses[148]. If this argument is correct, then all the previous case law and the doctrine of

[144] Commission Communication, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance), 2009/C 45/02 (24.02.2009), paragraph 85.
[145] R. WHISH and D. BAILEY, *supra* note 134, p. 748.
[146] EVRARD, *supra* note 98, p. 17.
[147] For a similar division see DAVIS, *supra* note 138, pages 14 -15.
[148] EVRARD, *supra* note 98, p. 15.

the essentials facilities could not be applied. As explained above, in order to apply the essentials facilities doctrine it is necessary to have a downstream market, precisely because its objective is to avoid the extension of a legal monopoly from an upstream market to a secondary market *(IMS, Magill*, etc.).



Opposite scenario: one market

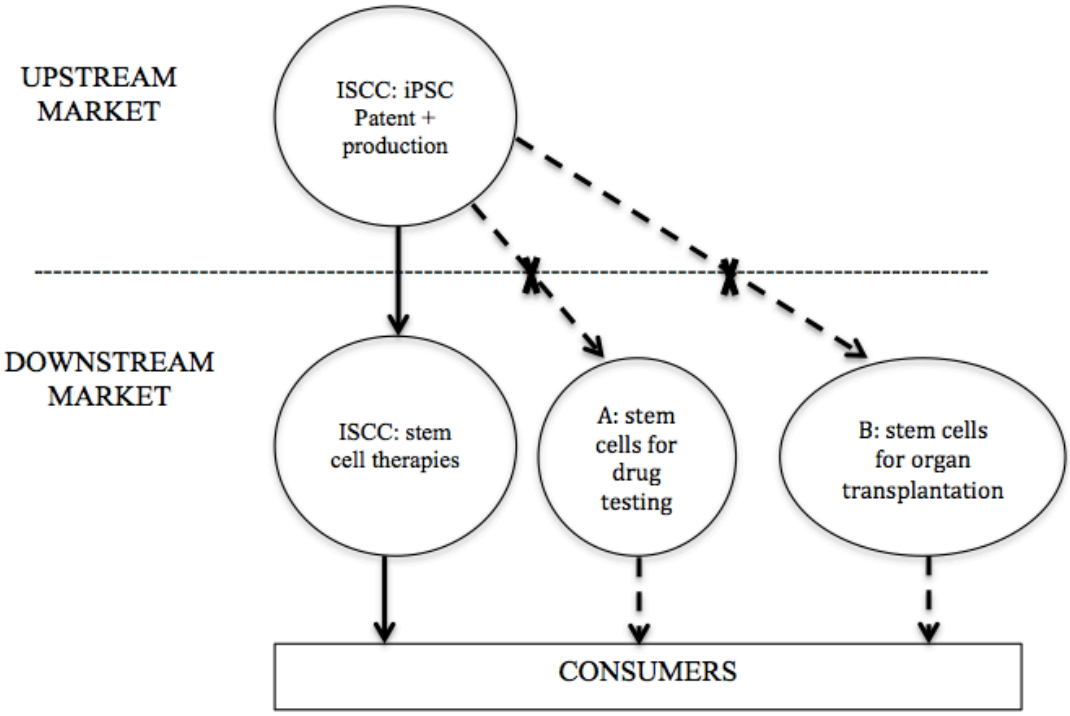
*Figure 3

However, there are strong reasons to believe that this separation is real. Some reports of non-European authors, with long culture in the biotechnological market, recognise this differentiation: "Within the biotechnology industry, upstream companies generally focus on conducting further research to add value to technology. The technology is then generally transferred to companies further downstream to be developed into commercial products"[149].

In the same line, taking into account that there are several downstream applications for human stem cells (cures for diseases, transplant of organs, drug testing), there is an apparent scientific demand for this input different from the demand of consumers for products developed by these last scientists[150]. It seems clear that a market of human stem cell production (protected here by a patent for the method of production) exists independently from the market where a scientist uses these cells into different consumer

[149] Australian Law Reform Commission, "Genes and Ingenuity", *Report 99*, 2004, p. 440. See also C. R. CARROLL: "Selling the Stem Cell: The Licensing of the Stem Cell Patent and Possible Antitrust Consequences", (2002) 2 *Journal of Law, Technology & Policy*, p. 454.
[150] EVRARD, *supra* note 98, p. 16.

products[151] (Figure 4).



Proposed Scenario: two markets

*Figure 4

Another reasonable counter-argument would consist in defining the secondary market broadly according to all possible therapies or cures for each specific application. This would include not only human stem cell therapies but also other methods. For instance, in the case of Parkinson's there have been two recent developments in its treatment, one based on stem cells[152] and the other on surgery using "impulse generators"[153]. This view has an inevitable consequence: the doctrine of the essential facilities cannot be applied now because iPSCs would not be an

[151] For an analysis of the case law about independent demand, including Microsoft, see H. SCHIMDT, *Competition Law, Innovation and Antitrust: An Analysis of Tying and Technological Integration*, Cheltenham, Edward Elgar, 2009, pages 73-74.
[152] J. JANKOVIC, W. POEWE, "Therapies in Parkinson's disease", (2012) 25 (4) *Current Opinion in Neurology*, pages 433-447.
[153] Although this treatment is originally based on hESC, the principal researcher recognises that the insufficiency of supply of stem cells would be solved with a more extended use of iPSC. See COGHLAN, "Fetal Cells injected to a man's brain to cure his Parkinson's", *New Scientist*, 26 may 2015. Available online: https://www.newscientist.com/article/dn27593-fetal-cells-injected-into-a-mans-brain-to-cure-his-parkinsons/ (Last accessed 21 April 2016).

essential facility. The undertakings could access to the downstream market of the therapy for a specific disease by using different sources[154] (Figure 5).

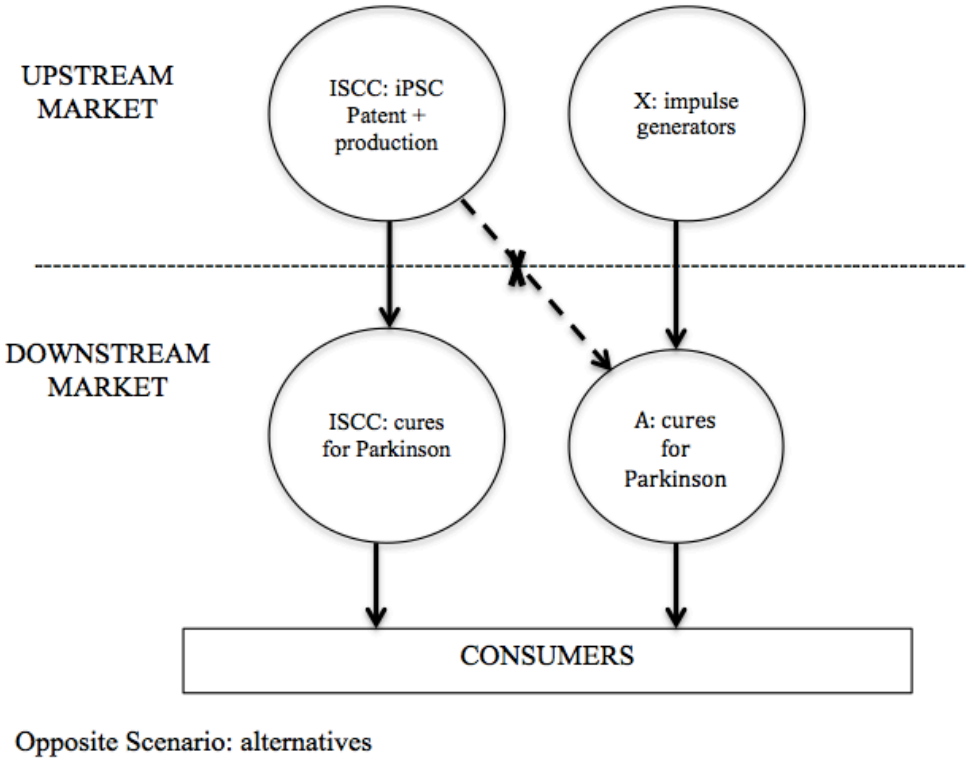
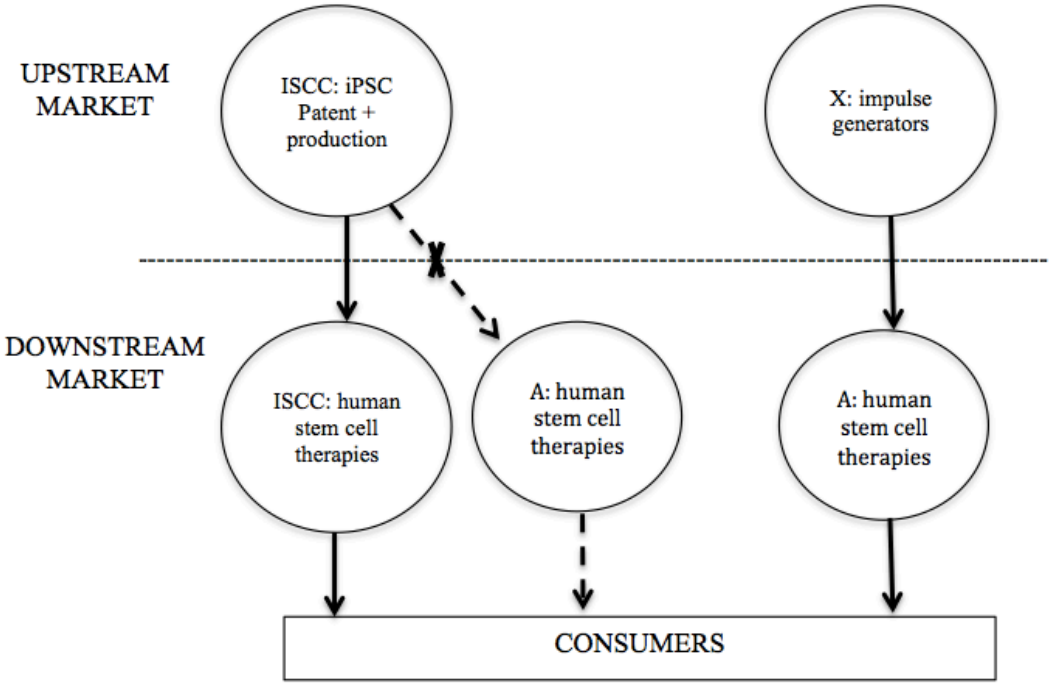


*Figure 5

In order to determine if there are effectively two or more substitutable products in the upstream market, namely stem cells and other sources like impulse generators, the ECJ established in the landmark case of *Continental Cans* that the EC must investigate the "characteristics of the products in question by virtue of which they are particularly apt to satisfy an inelastic need and are only to a limited extent interchangeable with other products"[155]. In order to apply this command, the EC has developed what is called the SSNIP test: in this case, if a Small but Significant Non-transitory Increase in Price would lead the scientists in the downstream market to abandon the more expensive source for the now more economic alternative[156].

[154] EVRARD, *supra* note 98, p. 16.
[155] Judgment in *Europemballage Corporation and Continental Can Company Inc. v Commission of the European Communities*, C-6/72, ECLI:EU:C:1973:22, paragraph 32.
[156]Commission Notice of December 9, 1997, on the definition of relevant market for the purposes of Community competition law, [1997] O.J. C 372/3, at 32.

Usually it is difficult to determine what evidences should be included in the scope of the test and how to obtain them without an empirical research of the market[157]. This is an analysis, unfortunately, beyond the scope of this legal thesis. However, the point of departure can be one simple assumption: the elasticity in not high between stem cells and other sources for therapies[158]. Even if the price of the impulse generators increases small but significantly, it is likely that the scientists would stay using the same technique. And exactly the same with an increase of the prices in stem cells: the mechanisms used to develop the therapies are so different depending on the source that it is unlikely they will shift the field of research[159] (Figure 6).



Proposed Scenario: no substitutability

*Figure 6

[157] R. WHISH and D. BAILEY, *supra* note 133, p. 35.
[158] EVRARD, *supra* note 98, p. 17.
[159] *Ibid.*

3. The refusal is likely to lead consumer harm.

In examining whether a refusal to supply or to grant a license can lead to consumer harm, the EC will see if the competitors are "as a result of the refusal, prevented from bringing innovative goods or services to market and/or where follow-on innovation is likely to be stifled"[160]. The initial "new product requirement", established by *Magill* and *IMS Health,* implied that the essential facilities doctrine could only be applied if the IPR holder was not active in the secondary market and if the product offered by the competitor was new and it had a potential consumer demand. In this sense, if the competitors were seeking to duplicate the product, no obligation to grant a license would be imposed. In the field of human stem cells, taking into account the dependency of the techniques from the stem cell, it would be extremely difficult to prove that the product proposed is be completely "new" and therefore the essential facilities doctrine would rarely be applied[161].

However, after *Microsoft* the EC decided to follow this more generous approach to the obligation to license including the criteria of "technical development". In this specific field, the possibility to prove that the product proposed includes an innovative element in comparison to the basic one produced by ISCC would be more reasonable[162]. If a scientist or pharmaceutical company in the downstream market can prove that the therapy based on iPSCs[163], in kidneys' regeneration for example, constitutes an improvement in comparison to the one offered by ISCC, he could claim a license over iPSCs in order to develop the therapy for commercial purposes[164].

[160] Commission Communication, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance), 2009/C 45/02 (24.02.2009), paragraph 87.
[161] BAKARDJIEVA ENGELBREKT, *supra* note 45, p. 392.
[162] *Ibid*.
[163] The research with iPSC would have been realised without authorization of the right holder thanks to the research exemption. For a description of this regulation in Europe, see A. KUPECZ *et al*., "Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement", (2015) 33 *Nature Biotechnology*, pages 710-715.
[164] For an analysis of different possible therapies based on iPSC, see S. YOKOTE and T. YOKOO, "Stem cells in kidney regeneration", (2012) 19 (5) *Current Medicinal Chemistry*, pages 6009-6018.

Chapter 2. Limits to the essential facilities doctrine.

1. Objective justifications

In order to accept a justification for a refusal to license or to supply, the EC will consider the impact on innovation in the market, including the own incentives of the IPR holder to innovate:

> "The Commission will consider claims by the dominant undertaking that a refusal to supply is necessary to allow the dominant undertaking *to realise an adequate return on the investments required to develop its input business*, thus generating incentives to continue to invest in the future, taking the risk of failed projects into account. The Commission will also consider claims by the dominant undertaking that its own innovation *will be negatively affected by the obligation to supply*, or by the structural changes in the market conditions that imposing such an obligation will bring about, *including the development of follow-on innovation by competitors*"[165].

A defender of the patent protection at all costs would consider that "the patent system remains the bedrock of future research both for new medicines and new medical devices"[166]. By forcing IPR holders to grant licenses, the EC would be "pushing for instant gratification in the shape of lower prices to consumers now at the expense of the benefits of delayed gratification in the shape of innovation for the future"[167]. In the sector of pharmaceuticals, for instance, the EC would "have weighed in heavily in favour of the copyists and against the inventors"[168]. For this author, the situation of the IPR holder when he is promised to receive the benefit of a monopoly and then it is reduced is comparable to the story of Hamelin, when the Major offers him fifty

[165] Commission Communication, Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance), 2009/C 45/02 (24.02.2009), paragraph 89. Emphasis added.
[166] R. JACOB, *supra* note 53, p. 16.
[167] *Ibid.*
[168] *Ibid.*

thousand guilders to eliminate the rats and, after the task was finished, he changed the offer to fifty guilders only[169] .

On the other hand, an important sector of the doctrine has serious concerns about the protection of biotechnological inventions in early stages because it would retard development in the downstream market[170]. In this sense, the effects of the patent in the downstream market should be taken into account before granting all the rights related to it[171]. Or, following the words of the previous poem, that authorities must not promise a thousand guilders when the real reward is going to be fifty due to the obligation to give licenses to competitors.

However, it is not necessary to take a position of IP "by all means" or competition law "at all costs". The essential facilities doctrine can in fact provide a respectful solution for both sides. First, the license does not have to be granted for free: the royalties can be established at a reasonable level and it can constitute itself an incentive to invest in research and development[172]. Second, the biotechnology field can constitute a sector with more incentives apart from a possible legal monopoly or licenses: the first mover, which puts the product into the market for the first time even without a patent, has the advantage to be in the market. This means consumers' feedbacks, creation of a network without competition, establish a significant brand loyalty, etc.[173]

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[169] *Ibid.*

[170] See J. NIELSEN, "Reach-Through Rights in Biomedical Patent Licensing: A Comparative Analysis of their Anti-Competitive Reach", (2004) 32 *Federal Law Review*, page 169; and M. ALLARAKHIA and A. WENSLEY, "Innovation and intellectual property rights in systems biology", (2005) 23 *Nature Biotechnology*, pages 1485-1488.

[171] R. JACOB, *supra* note 53, p. 16.

[172] EVRARD, *supra* note 98, p. 17. However, some authors criticise the substitution of contractual freedom for a simple remuneration, see F.-X. TESTU and S. HILL, "Le prix de la licence de brevet dans les hautes technologies: l'exemple des biotechnologies", (2008) 9 *La Semaine juridique - Entreprise et affaires*, pages 11-16.

[173] For a deep analysis of the advantages of the "first mover", see M. LIKHOVSKI, M. SPENCE, M. MOLINEAUX, "The First Mover Monopoly, a study on patenting business methods in Europe", (2000) *Oxford Electronic Journal of Intellectual Property*, November; C.W.L. HILL, M.A. SCHILLING and G.R. JONES, *Strategic Management: Theory & Cases: An integrated Approach*, Canada, Cengage Learning, 2016, pages 220-222; M. HERDER and R. GOLD, "Intellectual Property Issues in Biotechnology: Health and Industry", (2008) Report for the Third Meeting of the Steering Group, OECD International Futures Project on "The Bioeconomy to 2030: Designing a Policy Agenda" pages 6-11.

2. The fast way to get an obligation to license? Paragraph 82 of the Guidelines

The test of the essential facilities can be applied without interferences when the holder of the IPR has received exclusively private funding for his research. However, paragraph 82 of the *Guideance* gives the possibility to impose an obligation to grant licenses without considering the elements of "exceptional circumstances" previously analysed. This paragraph contains what is known as the "Telefónica exceptions"[174]:

> "In certain specific cases, it may be clear that imposing an obligation to supply is manifestly not capable of having negative effects on the input owner's and/or other operators' incentives to invest and innovate upstream, whether *ex ante* or *ex post […]*.
>
> This could also be the case where the upstream market position of the dominant undertaking has been developed under the protection of special or exclusive rights *or has been financed by state resources*. In such specific cases there is no reason for the Commission to deviate from its *general enforcement standard* of showing likely anti-competitive foreclosure, *without considering whether the three circumstances referred to in paragraph 81 are present"*.

As a result, if the IPR holder has received public funding the possibilities to impose an obligation to license are broader than in the case of private funding, because it is not necessary to pass this previous three-step test. This can be especially relevant in the field of human stem cell research because there are numerous projects directly funded, according to the laws of research of each Member State, by the EC in the framework of Horizon 2020[175].

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[174] Judgment in *Telefónica, SA y Telefónica de España, SA contra Comisión Europea*, T-336/07, ECLI:EU:T:2012:172. See also the Opinion of AG Mazák in Case C-52/09, *Konkurrensverket v TeliaSonera Sverige AB ,* delivered on 2 September 2010.

[175] For a description of the opportunities brought by Horizon 2020 to stem cell researchers, see the B. SUNDBY AVSET, "Horizon 2020: Opportunities for stem cell researchers", (2015) *12th Annual Norwegian Stem Cell Network Conference*. Available on: http://www.forskningsradet.no/prognett-stamceller/Nyheter/Horizon_2020_Opportunities_for_stem_cell_researchers/1254012779358 (Last Accessed 21 April 2016).

The problem, as it has been pointed out by NAZZINI, is that normally the undertakings receive both public and private investments[176]. Does this mean that it is necessary to assess the relative magnitude of them in order to determine which test to apply, the general test of article 102 TFEU or the essentials facilities' test?[177] This approach has been extremely criticised by the GERARDIN precisely because "it is difficult to apply in practice and is likely to lead to unpredictable and erroneous results"[178]. The reason why these exceptions should not be considered freely as a fast way to get an obligation to license has been correctly indicated by FAELLA and PARDOLESI: "they seem to open for a remarkable intrusion into the commercial freedom of dominant firms, which could negatively affect their incentives to invest and innovate"[179].

CONCLUSION

Human stem cells, and specifically iPSC, are a vital input for the development of one of the most promising fields of biotechnology. The possible applications of these cells can improve healthcare and the fight against some of the most serious diseases of our era. Consequently, public and private investment in research methods related to human stem cells has been increased considerably in the recent years. Universities, pharmaceutical companies, public and private medical institutes use these investments and the time of their teams to achieve medicals results that would have been considered impossible some years ago. The development of a method to create embryonic-like cells from adult stem cells, parthenogenesis, is one of the best examples.

The ethical concerns about the use of human stem cells have been, in a certain way, circumvented thanks to this new method and the judgment of the ECJ in *ISCC*. As a

[176] R. NAZZINI, *The Foundations of European Union Competition Law: The Objective and Principles of Article 102,* Oxford, Oxford University Press, 2011, p. 314.
[177] *Ibid.*
[178] D. GERARDIN, "Refusal to Supply and Margin Squeeze: A Discussion of Why the Telefonica Exceptions are Wrong", (2011) *Discussion Paper No 2011-009*, p.9. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1750226&download=yes (Last Accessed 21April 2016).
[179] G. FAELLA and R. PARDOLESI, "Squeezing Price Squeeze under EC Antitrust Law", (2009) p. 15. Available at: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1478937&download=yes (Last Accessed 21 April 2016).

result, the creator of this method can receive a patent which, in a certain manner, is a reward to his efforts and a tool to get his investment back with benefits. On the one hand, the IPR holder can refuse to give licenses to other undertakings. He would play here the role of Hera, using patent protection as a safe garden for the golden apples or iPSC. On the other hand, he can decide to give licenses to use iPSC to other undertakings. In this case, he would play the more admired role of John Appleseed, spreeding apple's seeds where necessary.

However, the refusal to give a license is not generally a reproachable behaviour. Contrary, it is the very essence of a right legally recognised in order to improve innovation. The possibility of acquiring a temporal monopoly over an invention gives an incentive to invest in research and development. If not, everyone could duplicate the invention without investing in previous investments. And, as a result, none would invest in new products and methods of research, with harmful consequences for the consumers.

In some circumstances the patent concerns a very broad tool, as parthenogenesis, which is essential for the follow-on innovation. If the IPR holder decides to impede the access to other competitors with his patent, the downstream innovation would be completely blocked. Here, the consequence of impeding the development of new products would be equally harmful for the consumers. The solution analysed in this thesis has been the application of the essential facilities doctrine, forcing the IPR holder to grant licenses under very specific circumstances. The case law from *Commercial Solvents* to *Microsoft* has developed little by little a more liberal approach to the essential facilities doctrine, very limited in its application at the beginning. Although the use of this competition law tool under article 102 TFEU is very exceptional, its application is more possible now thanks to these recent developments.

The idea of limiting the legal monopoly granted by a patent has been radically rejected by some author. In his words, with such an action the authorities would be "favouring grasshoppers, positively helping them sing in the summer (I.e. gathering profits now) and saying: do not worry, sing away, when winter comes we will make the ants feed

you"[180]. The alternative would be the death of the grasshopper because of winter. However, an undertaking which has not developed parthenogenesis first does not mean it is a grasshopper, simply that it is not the first one to achieve it but even that it has invested or is willing to invest on this technology.

The solution proposed by the essential facilities doctrine defended in this thesis does not grant free access to the home and supplies of the IPR holder. Compulsory license for essential inputs, under exceptional circumstances, would be granted only if royalties were paid, only if the "grasshopper" accepts to pay a fair price for the supplies. This seems to be a respectful solution for the interests of both inventors and consumers under the rules of competition law. This thesis is founded in a simple hypothetical definition of the market and not in irrefutable economic evidences. However, the potential issues analysed can constitute an important legal battlefield in the future, similar to the field of technologies of the information nowadays. The essential facilities doctrine could be an essential competition tool of solving them. A clear idea about the characteristics of this tool, namely when the exceptional circumstances can be fulfilled or not, would provide certainty to future disputes in this field. Or, quoting an old medical proverb, "prevention is better than cure".

[180] R. JACOB, *supra* note 53, p. 15.

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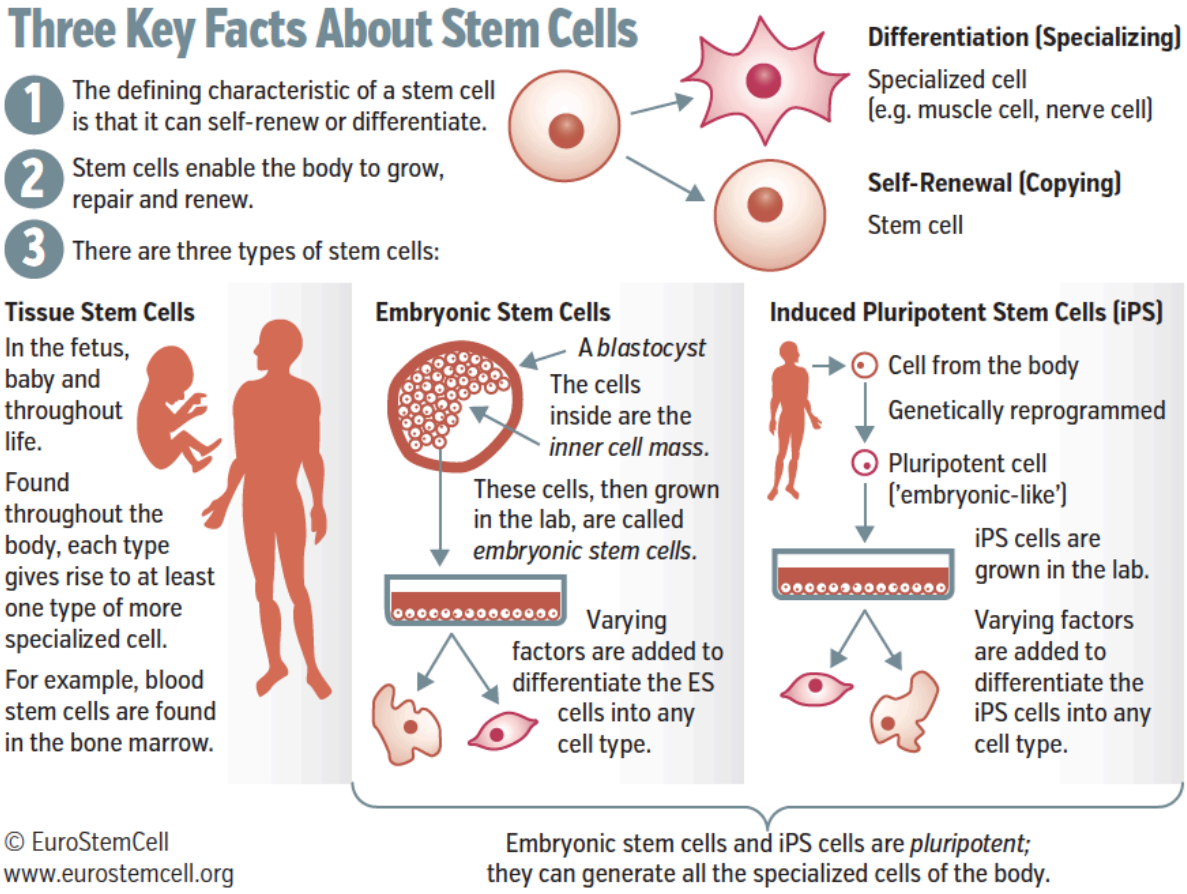
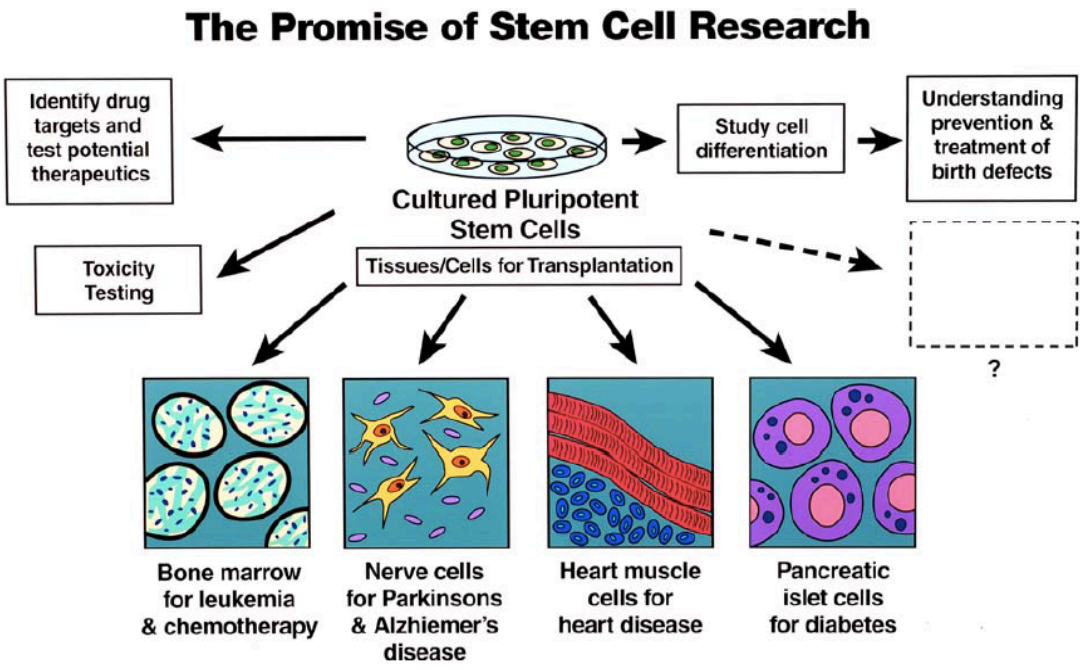
ANNEXES

ANNEX I: Key Facts About Stem Cells



ANNEX II: Applications of Stem Cell Research (source: Vicente González Díaz, *Mondays of Patents*, Madrid, 25 June 2007)



ANNEX III: European Patent System (source: UK Parliamentary Office of Science and Technology, Postnote number 401).