The Rhineland Biopatent Gazette

brought to you by Michalski Huettermann & Partner Patent Attorneys - Issue 2/2011

Duesseldorf/Munich, **07 August 2013** The times they are a'changing – particularly in the Biopatent discipline. Biopatent professionals live in a quickly developing world, which is sometimes hard to keep pace with. Michalski · Huettermann & Partner Patent Attorneys have decided to produce relief to this situation, and are proud to present a new information service related to Patent issues in Biotechnology. This newsletter issues on an irregular basis in order to provide information with respect to actual events, as well as in-depth-analyses of long-term developments. Patent Attorneys from our firm explain the meaning of actual decisions issued by European Patent authorities for the Biopatent community, and provide expert insight into what's going on behind the scenes. In this issue, William E. Bird, Principal of Bird Goen Co in Leuven, Belgium, with whom we are connected by our pan-european legal association "EIPLA", reports on a recent decision affecting the licensing of biotech patents. Further, Associate Dr. Andreas Hübel reports on the recently issued opinion of the Advocate General in the Brüstle case.

A licensing rule of thumb under the hammer – Ooch! ?

Licensing of biotech patents, especially the licensing of patented diagnostic and analytical kits, has been very important, e.g. for the income of University Tech Transfer departments as well as for early stage research in pharmaceuticals.

It is generally difficult to determine relevant license fees for patented technology and ideally the procedure for this should be a rapid, transparent and fair. One such rule that has been used a lot is the so-called "25% rule", that is 25% of the benefit provided by the invention goes to the patent owner, 75% to the exploiter of the patented technology. This split is thought to be a fair compensation for the increased effort, liability and costs of the licensee who markets the product compared to the licensor. The value of 25% is not hard and fast – one can adjust it to the facts of the case. But it gives a useful starting point. The "25% rule" has become a key tool of patent proprietors for determining royalty rates. However, this year started badly when, on January 4th, the U.S. Court of Appeals for the Federal Circuit abandoned the "25% rule".

Interestingly, Judge Joseph Longobardi of the District of Delaware observed in Procter & Gamble Co. v. Paragon Trade Brands, Inc., 989 F. Supp. 547, 612 (D. Del. 1997) that a "Rule-of-Thumb" was in use in patent cases for the estimation of royalty rates although he did mention that the Court had found no case adopting this test as a matter of law. The "Rule-of-Thumb" of Procter & Gamble, has gradually become better accepted and nowadays it figures prominently, for example, in our seminars and lectures for the Licensing Executive Society (LES) and in our master classes on Intangible Asset Management. In the case decided this year (Uniloc v. Microsoft) it was asserted by Uniloc that the 25% Rule is accepted as a proper base line

Advocate General considers embryonic stem cells not an embryo

but shall not be patentable either

With respect to the patentability of pluripotent embryonic stem cells, the Advocate General provided his opinion to the European Court of Justice which is concerned with the task of providing answers to questions referred to by the German Federal Court of Justice with respect to German Patent No. 197 56 864.

The patent is suit was granted on April 29, 1999 and comprises claims directed to isolated, purified precursor cells having neuronal or glial properties from embryonic stem cells, and to methods for producing such precursor cells. Greenpeace e.V. filed an annulment suit for having the patent annulled in so far as certain claims concern precursor cells obtained from human embryonic stem cells. Greenpeace considers the invention unpatentable under Article 2 of the German Patent Law. The Federal Patent Court (Bundespatentgericht) declared the patent invalid in so far claim 1 relates to precursor cells obtained from human embryonic stem cells and claims 12 and 16 relate to processes for the production of precursor cells. The patent proprietor appealed against this decision at the Federal Court of Justice (Bundesgerichtshof). The latter considers that the outcome of the proceedings will depend on the interpretation of certain provisions of Directive 98/44 (Biotech-Directive) and referred questions to the European Court of Justice concerning the meaning of the terms "human embryos" and "uses of human embryos for industrial or commercial purposes". In addition, the referring Federal Court of Justice wants to know, whether a technical teaching is be considered unpatentable pursuant to Article 6(2)(c) of the Directive even if the use of human embryos does not form part of the technical teaching claimed with the patent, but is a necessary precondition for the application of that teaching.

In his opinion, the Advocate General, Yves Bot, argues that the development of a human body starts with fertilization, and differentiation begins

+ from our firm +

Journal article by MH partners was awarded "Article of the month" by LES

One article written by authors from our firm has now been awarded "Article of the month" in Les Nouvelles, which is the official journal of the Licensing Executives Society (LES).

The article written by Dr. Aloys Huettermann and Dr. Ulrich Storz is related to the Monsanto soy bean cases, and is titled "Monsanto Soy Bean Patent Cases— A Paradigm Shift Gathering In Case The ECJ Takes Over Patent Jurisdiction".

To see the full article of the month, please click here.

MH partners will attend the BIO Convention in Washington in June 2011

Two partners of the firm, Dr. Uwe Albersmeyer and Dr. Ulrich Storz, will attend the BioConven-

from which to start.

Not to say that the rule has not received criticism. The outcome of licensing deals varies greatly and it has often been argued that one rule could/would not be suitable for all. Traditionally, licensing negotiations are very dependent upon the facts and on the "leverage" that the parties bring to the table. Such "leverage" can be, for example, market dominance of the relevant party, strength of the patent(s), the ease of designing around, geographical location, windows of opportunity, alternative bidders, etc. Some companies are prepared to sell at no profit in order to introduce a product to the market, i.e. they are prepared to accept zero benefit in exchange for market penetration which would translate into a royalty rate of 100% rather than 25 if such facts were to apply to the particular case.

As usual bad law comes from bad cases/facts.

In the case in question, Uniloc had sued Microsoft alleging that a feature of Microsoft's Word and Office Suite software infringed Uniloc's US Patent No. 5,490,216. At trial Uniloc submitted calculations based on a hypothetical negotiation between Uniloc and Microsoft relying in part on the "25 % rule." The problem was that when the calculation of the total damages was made it amounted to over half a billion dollars. At first instance the jury returned a verdict of infringement, found the patent valid and wilfully infringed, and awarded $388 million in damages. Microsoft believed that the "25% rule" was illegally arbitrary and hence appealed to the Federal Circuit. The problem is really the final total figure – it seems inappropriate to use a rather arbitrary rule when the final calculation comes to hundreds of millions of dollars. As indicated above 25% is not cast in concrete – one can vary it quite significantly. So one could call it the "25±10% rule". In a case like Uniloc v. Microsoft, it would seem not only appropriate but even essential to spend more time and money on a more accurate assessment, e.g. when a 1% error means $4 million why not spend $500,000 getting a more accurate result? Using the Rule of Thumb in an inappropriate situation should not invalidate the rule. However, one bad case makes the rule bad for all – that is not really justifiable – but an unfortunate consequence of the way the system works.

In many early stage licensing scenarios there is a lot of uncertainty and there is a need for some way of agreeing on a royalty rate. The loss of a simple and persuasive, even if rather arbitrary, rule, places the licensing community in a state of uncertainty. Other starting points for estimating a reasonable royalty can be more expensive and could be just as, or even more arbitrary, than the rule they have to replace.

The Federal Appeal Court in its decision this year refers to the long list of so-called Georgia-Pacific factors set forth in Georgia-Pacific Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116 (S.D.N.Y. 1970). However, no method of calculating these factors is provided and they form a heterogeneous collection of factors requiring rather vague and arbitrary considerations. They certainly lack the

with a few cells, which exist in their original state for only a few days. Each of these totipotent cells has the capacity to develop into a complete human being. The full capacity for subsequent development is therefore concentrated into one cell. Therefore, the concept of a human embryo applies from the fertilisation of an ovum by a sperm via the initial totipotent cells and to the entire ensuing process of the development and formation of the human body. As each totipotent cell can form an entire body. Thus, totipotent cells represent the first stage of the human body which they will become. Therefore, they have to be legally categorized as embryos, any patentability should be excluded under Article 6(2)(c) of Directive 98/44. In addition, a blastocyst is the product of the totipotent cell's capacity for development at a certain moment. The blasotcyst is therefore one stage in the development of the human body. Accordingly, a blastocyst has to be categorised as an embryo, like any stage before or after that development.

Very early in its development, the embryo shows differentiation as the blastula consists of an epithelial-like outer cell layer and an inner cell aggregation. The embryo is then formed of pluripotent cells, but no longer of totipotent cells. The pluripotent cells can develop into all kinds of cells, gradually to form all the organs of the human body. Unlike totipotent cells, individual pluripotent cells cannot develop into a complete human being. They are the product of some differentiation and a sign of diversification which will result in specialisation and diversification as the cells multiply. Pluripotent embryonic stem cells are not capable of resuming the development of the human body when they have been removed from the blastocyst. As pluripotent cells they can not lead to a complete human being. the Advocate General deems that pluripotent embryonic stem cells, taken in isolation, cannot be categorised as human embryos. Hence, pluripotent embryonic stem cells are not excluded from patentability under Article 6(2)(c) of Directive 98/44.

However, the Advocate General stated that the origin of the pluripotent cell can not be ingnored. In the present case the pluripotent stem cells are removed from the blastocyst which will be destroyed thereby. As the blastocyst itself is categorized as an embryo, the removal of the pluripotent stem sells destroys the embryo they are removed from. Even though the claims of the patent in suit do not specify that human embryos are used for the exploitation of the invention, they actually are and the patentability of such an invention has to be excluded. This would not be the case, if the removal of the pluripotent stem cells would not result in the destruction of the embryo regardless of its developmental stage. But the Advocate General considers that an invention has to be excluded from patentability, where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryoes.

In summary, the Advocate General recommends the European Court of Justice to answer the questions referred to by German Federal Court of Justice in that Article 6(2)(c) of Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions must be interpreted as follows:

– The concept of a human embryo applies from

tion in Washington in June 2011. Please send us an email here if you would like to arrange a meeting.

Feedback please !

What do you think about this newsletter ? Let us have your comments here.

Archive

In the future, you may find prior issues of the Rhineland Biopatent Gazette here.

simplicity of the “25% rule”.

The rejection of the “25% rule” can be seen as part of a tendency in patent law to shy away from “one-size-fits-all” rules and to go to a more evidence based approach relying more on empirical data. However, licensing negotiations often involve a large number of unknown variables and facts can be scarce. Hence, the opportunities for stagnation of the deal are high. Any rule that makes life simpler and prevents the negotiation tripping over matchsticks is welcome!

If the “25% rule” is gone forever then a new approach is required that gives the parties cost-effective guidance for royalty fee calculations. But just maybe we simply ignore the Federal Circuit court and continue as we did before - as long as there is no risk of ending up in front of a US court! We can always try and distinguish over Uniloc v. Microsoft – that case was about calculating damages based on a hypothetical licensing deal. That is nothing like a real licensing deal.

the fertilisation stage to the initial totipotent cells and to the entire ensuing process of the development and formation of the human body. That includes the blastocyst.

– Unfertilised ova into which a cell nucleus from a mature human cell has been transplanted or whose division and further development have been stimulated by parthenogenesis are also included in the concept of a human embryo in so far as the use of such techniques would result in totipotent cells being obtained.
– Taken individually, pluripotent embryonic stem cells are not included in that concept because they do not in themselves have the capacity to develop into a human being.
– An invention must be excluded from patentability where the application of the technical process for which the patent is filed necessitates the prior destruction of human embryos or their use as base material, even if the description of that process does not contain any reference to the use of human embryos.
– The exception to the non-patentability of uses of human embryos for industrial or commercial purposes concerns only inventions for therapeutic or diagnostic purposes which are applied to the human embryo and are useful to it.

See the full text of the opinion here.

Michalski Huettermann & Partner are getting personal... Today: Dr. Johanna Driehaus

Johanna Driehaus, born in 1982, studied Biotechnology and Life Sciences in Germany and the UK, where she obtained her M.Sc. degree in 2005. Between 2005 and 2008 she conducted the work for her PhD thesis in the field of human embryonic stem cell research at the University of Bonn. Johanna underwent her Patent Attorney training at MH Patent, where she specialized in issues related to molecular diagnostics. Johanna is currently working as an intern at the German Patent Office (DPMA) nd the Federal Patent Court (BPatG)

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