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Biotechnology Directive: human parthenotes

Summary

The European Court of Justice (ECJ) has held that human parthenotes, which are incapable of developing into a human being, are not excluded from patentability under the Biotechnology Directive (98/44/EC) (the Directive).

Background

EU member states must protect biotechnological inventions under national patent law (*Article 1(1), the Directive*). Article 5(1) of the Directive excludes from patentability the human body, at the various stages of its formation and development, and the simple discovery of one of its elements.

Inventions are unpatentable where their commercial exploitation would be contrary to “ordre public” or morality (*Article 6, the Directive*) (Article 6). Under Article 6(2)(c), the use of human embryos for industrial or commercial purposes is unpatentable.

In *Oliver Brüstle v Greenpeace eV*, the ECJ held that a non-fertilised human ovum was classified as a human embryo within the meaning of Article 6(2)(c) in so far as it was capable of commencing the process of development of a human being (C-34/10).

Facts

Its two UK patent applications relating to human stem cells were rejected by the examiner. On appeal, the intellectual property office hearing officer held, following *Brüstle*, that the inventions disclosed in the patent applications were excluded from patentability under paragraph 3(d) of Schedule A2 to the Patents Act 1977, which implements Article 6(2)(c), and he also rejected the patent applications. I appealed.

The High Court asked the ECJ whether 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, are included in the term “human embryos” in Article 6(2)(c).

Decision

The ECJ held that, in order to be classified as a human embryo, a non-fertilised human ovum had to have the inherent capacity of developing into a human being. Where a non-fertilised human ovum did not fulfil that condition, the mere fact that organism commenced a process of development was not sufficient for it to be regarded as a human embryo for the purposes of the application of the Directive. By contrast, where such an ovum had the inherent capacity of developing into a human being, it should for the purposes of Article 6(2)(c) be treated in the same way as a fertilised human ovum, at all stages of its development.

The High Court had stated that, according to current scientific knowledge, a human parthenote, due to the effect of the technique used to obtain it, was not capable of commencing the process of development that led to a human being. That assessment was shared by all of the interested parties that submitted written

observations to the court. In addition, I had amended its applications to exclude the prospect of the use of additional genetic manipulation.

It followed that this case related solely to the classification of a human parthenote in itself, and not of a parthenote that was the subject of additional manipulation falling within the scope of genetic engineering. It was for the High Court to determine whether or not, in the light of current international medical knowledge, human parthenotes had the inherent capacity of developing into a human being.

Comment

Parthenotes are cells that are not fertilised but stimulated by parthenogenesis to divide and grow like human fertilised eggs, but are incapable of completing the process of development into a human being. They are used, for example, in stem cell research. Provided that they have not been genetically modified to acquire the capacity to develop into a human being, parthenotes are not human embryos and are therefore patentable. If, however, a parthenote is genetically altered so that it becomes capable of becoming a human being, it would cease to be patentable.

The biotechnology industry in the EU will be relieved that the ECJ has confirmed the patentability of human parthenotes that are incapable of developing into a human being. I's patent applications concerning the development of a method of obtaining human pluripotent cells can now proceed to the normal examination process. However, the ECJ has observed that inventions involving further genetic engineering of the parthenote risk being unpatentable as they will raise again the question of whether there is the inherent capacity to develop into a human being.

Case: *International Stem Cell Corporation v Comptroller General of Patents C-364/13*.

Data Protection Directive: CCTV surveillance

Summary

The European Court of Justice (ECJ) has held that the Data Protection Directive (95/46/EC) (the Directive) applies to CCTV installed by a person on his family home for crime prevention purposes and directed towards the public footpath and neighbouring house.

Background

The Directive imposes broad obligations on those who collect personal data and confers broad rights on individuals about whom data are collected. Personal data is defined as any information relating to an identified or identifiable natural person (Article 2(a), the Directive) (Article 2(a)). The Directive does not apply to the processing of personal data by a natural person in the course of a purely personal or household activity (Article 3(2), the Directive) (Article 3(2)).

Facts

In response to attacks on his property, R installed a CCTV camera system at his family home, to protect his property, health and the lives of his family and himself. The CCTV recorded the entrance to his home, the public footpath and the entrance to the house opposite. The CCTV recorded on a hard disk drive visual images, but no audio sound, on a continuous loop. Only R had direct access to the CCTV system and the data.

During one attack on R's home, the CCTV made it possible to identify two suspects. R handed the recording to the police and this evidence was relied on in the criminal proceedings that followed.

One of the suspects sought clarification from the Office for Personal Data Protection in the Czech Republic (the office) as to whether or not R's use of the CCTV was lawful under Czech law. The office found that R had infringed the relevant law as follows:

- As a data controller, he had used the CCTV to collect, without the data subject's consent, the personal data of people on the public footpath or entering the house opposite.

- He had not provided a privacy notice to inform people that: the CCTV was in place and was processing their personal data; the extent and purpose of that processing; by whom and by what means the personal data would be processed; or who would have access to the personal data.
- He had not notified the office that he was processing personal data.

R's challenge to the office's decision, on the basis that his use of the CCTV was exempt under Article 3(2), was dismissed. R appealed to the Supreme Administrative Court of the Czech Republic, which referred the question to the ECJ for a preliminary ruling.

Decision

The ECJ held that for the purposes of the exemption for purely personal or household activity in Article 3(2), CCTV installed by an individual on his family home to protect the property, health and life of the home owners, but which also monitors a public space, does not amount to processing of personal data in the course of a purely personal or household activity and, therefore, falls within the scope of the Directive.

The image of a person recorded on a camera constitutes personal data within the meaning of Article 2(a) because it makes it possible to identify the person concerned. Video recording of individuals on a continuous recording device on a hard disk drive constitutes, under Article 3(1) of the Directive, the automatic processing of data. The processing of personal data falls within the Article 3(2) exemption only where it is carried out in the purely personal or household setting of the person who is processing the data. As the CCTV surveillance covered (or even partially covered), a public space and was directed outwards from the private setting, it could not be regarded as an activity that is a purely personal or household activity.

The ECJ noted that, in certain circumstances, the exemptions and restrictions within the Directive, in particular the pre-conditions to processing, make it possible to take into account the legitimate interests of the data controller (such as the protection of his property, his health and the life of his family and himself), which may permit lawful processing.

Comment

This decision may be seen as part of a series of cases strengthening individuals' rights, such as Google Spain SL and Google Inc v Agencia Española de Protección de Datos (AEPD) and Mario Costeja González (C-131/12; see News brief "Google decision: the right to be forgotten", www.practicallaw.com/3-568-9605). The ruling has significant implications for the way that CCTV can be used at home, if the CCTV even partially records a public space. The UK Information Commissioner has indicated that it will update its code of practice on CCTV and other surveillance technologies in the light of the judgment.

The decision may also have broader implications for the way that other recording devices may be used in public spaces; for example, drones, body-worn video and wearable computing such as watches or glasses. It is unclear if the ECJ would have reached the same conclusion if the device in question had been a camera rather than a continuous video recording.

Case: *František Ryneš v Úřad pro ochranu osobních údajů C-212/13*.

Patents: guidance on product by process claims and obviousness

Summary

The High Court, applying the European Patent Office's (EPO) approach to the allowability of product by process claims, has refused to allow proposed amendments to the claims of two patents for a breast cancer drug.

Background

If the invention is a process, a person infringes the patent for that invention if he disposes of, offers to dispose of, uses, imports or keeps (for disposal or otherwise) any product obtained directly by means of that process (section 60(c), 1977 Act) (1977 Act).

In considering whether or not to allow a proposed amendment, the court or the comptroller shall have regard to any relevant principles applicable under the European Patent Convention (section 75(5), 1977 Act).

Facts

G's patents related to formulations of the breast cancer drug known as Herceptin, whose active ingredient is trastuzumab. Patent protection for trastuzumab itself had expired. The patents related to lyophilised (freeze-dried) formulation of antibodies, one of which was trastuzumab. G applied to amend both patents and did not defend the validity of the relevant claims as granted.

H argued that all of the claims as amended were obvious, or, if not obvious, were insufficient. H also contended that none of the amendments proposed should be allowed, on four grounds: extension of scope; a point on product by process claims; clarity; and added matter.

Decision

The court held that the proposed amendments were not allowable under the EPO principles relating to product by process claims, also that they introduced added matter, and that all of the claims in issue lacked inventive step.

There are two kinds of product by process claims: products obtained by a process; and products obtainable by a process.

A new process that produced a product identical to an old product could not confer novelty on that product. To be novel a product obtained or obtainable by a process had to have some novel attribute conferred on it by the process as compared to the known product. This rule was a rule of the law of novelty, not a principle of claim construction. Although, in effect, the rule treated "obtained by" in the same way as "obtainable by", as a matter of claim construction a claim to a product "obtained by" a process meant what it said. That would be the relevant scope of the claim as far as infringement and sufficiency were concerned.

Although normally a patent was drafted by the inventor in words of his own choosing, the EPO would not permit overt product by process language unless there was no other way of defining a particular characteristic of the product in question.

Here, the proposed amendments were unallowable because they did not state which characteristic of the product conferred by the process is being referred to. The skilled reader would not know, from the claim or the specification as a whole, which one was intended. Unless it is possible to identify all the attributes to which the language applies, amendments to this type of claim cannot be permitted.

In relation to obviousness, the law could not be accurately summarised simply by stating that the question was whether the skilled person would have arrived at the claimed invention, not whether they could have. The issue depended on the facts. Sometimes asking simply if a skilled person would do something risked placing too much weight on minor or irrelevant factors like cost, instead of focusing on the technical issues. The fact that the claimed invention was not something a skilled person would in practice make was not relevant. It was more accurate to say that it was not patentable because the skilled person could make it without any inventive step. However, in other cases the difference between "could" and "would" was important. If the outcome rested on the result of a single experiment, the fact the skilled person could carry it out did not usually mean the invention was obvious: the question may be whether they would carry out the test in the expectation of a positive result.

Here, it was not true that a real team would arrive at the claimed formula. However, the claimed formula could be reached by applying nothing other than the routine approaches applied to excipients that were part of the skilled team's common general knowledge. This was not a case where the invention was not obvious because it was only arrived at after a series of steps involving the cumulative application of hindsight, that is where it was only the hindsight knowledge of the invention as the target that could motivate a skilled person to take each step without knowledge about the next one. So, all of the claims lacked inventive step.

Comment

Applying EPO principles relating to amendment of product by process patents, the UK court refused amendments that did not allow the reader to identify all the attributes of the product conferred by the process conditions. To identify one attribute was not sufficient if the reader would understand there was likely to be an indefinite class of further attributes to which the product by process language also applied.

This decision also addresses the law of validity and infringement in relation to product by process claims, which are typically in the form of “obtained by” or “obtainable by”. To be novel a product obtained or obtainable by a process has to have some novel attribute conferred on it by the process as compared to the known product. However, for an “obtainable by” claim to be infringed if a different process is used, it must have every single characteristic that is the inevitable consequence of that process. If one attribute is missing then it is not “obtainable by”. In practice, it may be difficult if not impossible to demonstrate infringement of an “obtainable by” form of claim if a different process is involved from that specified in the claim.

The court's analysis of obviousness in the context of a drug formulation case is also interesting. The relevant approach may depend on the facts: in an empirical field the skilled team will, without hindsight, want to test a range of ingredients that are all part of the common general knowledge, and this will not necessarily involve an inventive step.

Case: *Hospira UK Ltd v Genentech Inc* [2014] EWHC 3857 (Pat).



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