

INGENIOUS

Appellant

My lords, we come from France and we represent Nantes' university of law.

Do you want us to sum up the facts which are carried to your appreciation today?

Based on one of its employee's research which was kept secret since 2004, Ingenious Labs Inc applied for the patent of the CT protein before the Patent Office of Erewhon on 17 September 2005. The 'Cyston T protein produced by recombinant technologies' patent was granted by the POE in March 2008.

Since September 2008, Erewhon Health Corporation has started producing its own synthetic CT protein by recombinant technologies, using a different bacterium as the host cells

This production has occurred without the permission of Ingenious. So this conduct infringes its synthetic protein patent.

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Intellectual property laws prevent intellectual rights from infringements. To that aim, they draw the line between what is prohibited and what is allowed. An honest economic player has to be able to follow a normal activity with his protected rights.

So, if you agree,

Firstly, I will submit that the invention is not patentable because of its nature, its non novelty and its contradiction with the *public policy*.

Then, Dimitri will submit that the patent was granted even if

I. On the patentability of the invention process

A. On the discovery

Concerning the notion of invention, The High Court correctly decided that “the claim adds more subjects matter, attaching insights pertaining to the artificial production of the protein for which the CT gene encodes”

In virtue of article 21, a discovery is not in itself patentable, but legal precedence agrees that a process applied to a discovery is.

According to these articles a discovery is not patentable by itself. Must we then consider the patent registered by my client as a discovery? The answer to this question is undoubtedly no because we have to distinguish between the discovery and the process applied to this discovery.

Articles 20 and 21 can be interpreted in light of directive 44/98¹ which accepts this principle and states that *"an element isolated from the human body or produced otherwise is not excluded from being patented, because it is, for example, the result of technical processes which identified, purified, characterised and multiplied it outside the human body, techniques (...) that nature is incapable of achieving itself"*.

This principle has often been recognised in French case law

Thus with regard to the law established at both a national and a community

1 Community Directive 44/98 of 6 July 1998.

level, the process applied to a discovery is patentable. Keep in mind then that the patent filed by "Ingenious" does not refer directly to CT protein but instead to the process of combining the protein with the bacterium *E.coli*. This is therefore an industrial process which, although concerning a discovery, is liable to be patented.

Taking the above into account, the ECH cannot assert, without discounting the definition of a patent, that a discovery has been patented. As it is based on an invention, the patent cannot be cancelled on the ground of article 27a.

B. On *Ordre public*

The High Court has equally ruled on another aspect of the patent. L'ordre public.

Effectively article 22 of the Erewhon Code which states that "patents are not to be granted in respect of invention the commercial exploitation of which would be contrary to ordre public or morality"

This article can also be interpreted in relation to directive 44/98. the directive excludes a living element, it specifically accepts genetic sequences, once they have been isolated or duplicated by a technical process, even if their structure is identical to the original existing in nature².

Similarly, the EPO evokes a limitation to the exception in *ordre public* by stating that "*an element isolated from the human body or otherwise produced by a technical process, including gene sequencing or partial sequencing, can constitute a patentable*

2 Article 5-2 Community Directive 44/98 of 6 July 1998.

*invention, even if the structure of this element is identical to that of a natural element*³".

The patent filed by "Ingenious" meets these criteria. Indeed, the claim is based on the synthetic reproduction of CT protein, Even if the patent concerns a human gene, what is protected is the technical combination process. Again, we must do the difference between the process (here the combinaison) and the protein on which is this process.

This is therefore a patentable invention in the sense of the directive. It meets the conditions of article 22 and must not be revoked.

C. On the novelty of the invention

Concerning the novelty of the invention, the High Court has ruled that "the newness of the claim to CT protein produced by recombinaison can not be impugned on the basis of the prior existence"

This corresponds to the application of articles 20 and 23. To assess novelty, article 23 states that there must be "*divulgence to the public via written or oral description, usage or any other means*".

We asked the judges to consider that although rCT protein is very close to niCT protein, the process used to obtain it is unique. Indeed, it involves encoding a human protein using a process which no longer requires blood donation (as it did previously) because it is synthetic.

³ EPO, 8 December 1994, Relaxine.

Indeed, the patent application does not concern the natural CT protein but the recombination process which enables it to be produced synthetically. "Ingenious" also added that the two proteins, niCT and rCT, are absolutely not identical from the point of view of glycosylation.

However, the patent application was filed on 17 September 2005 and was awarded by the Erewon Patent Office in March 2008. "Ingenious" kept the results of this research secret until the patent application was filed but it can be supposed that they started to use it from the date of filing. Furthermore, in 2000, part of Dr Pollack's work was published in *"Book of Life"*, notably concerning the identification of the human gene which produces CT protein.

Furthermore, the previous judges had ruled in favour of "Ingenious" by recognising that the two proteins are different. Moreover, they noted that it was impossible to obtain such a product without the results of the research performed by Dr Pollack which was only completed in 2004.

Thus the only precedence is that the pre-existence of niCT protein does not prove the non-novelty of the invention, that's to say the combination of the protein and the bacterium.

D. On the inventive step

Finally considering the inventive step, the High Court judged that "if on the basis of that discovery it can tell people a way how the discovery can be usefully employed, then a patentable invention may result"

The condition of inventive step is found in articles 20 and 23. It is similar to the idea

of non-evidence. It is a subjective condition revealed through a series of indices.

These articles can be construed in light of art 56 EPO⁴ which sets out that « an invention is considered to contain an inventive step if, to a person skilled in the arts-specialist, it does not obviously follow from the state of the technique».

From this, many indications allow a characterization of the condition. Firstly the invention poses a technical problem which is not presented in the previous (p176 - 4)

Moreover, the creation of the invention encounters technical difficulties (12).

The difficulty overcome by years of research on the part of Dr Pollack permits the classification of an inventive step. Finally let us not forget economic advantages gained, as they represent important technical progress (7-5)

"We have already specified that its invention is the result of an inventive step. Based on this argument, it considers that the result of Dr Pollack's research was unexpected and unpredictable in so far as he was the first person to isolate this gene and work from this basis, and that this represents significant technical progress.

The lower courts had also replied positively to this argument, considering that the claim does not concern the gene but that "Ingenious" has really provided the public with a process enabling the discovery to be used, which therefore proves the existence of an inventive step.

Finally, concerning the investment, the fact that a company is investing so much in

4 A METTRE DANS LE BUNDLE !!!!

research work demonstrates how far the result obtained is not obvious and can be considered to reflect inventive activity.

Thus the patent fulfils the condition of inventive step, as well as all the conditions settled by article 27a.

Let's turn our attention now to article 27b which my colleague shall examine.

II. Request for revocation of the patent on the grounds of article 27(b)

Intro

My Lords, I will study with you the application of the article 27b, about the revocation and the infringement of the patent.

A. La révocation

Concerning the revocation of the patent on the grounds of article 27(b) « Ingenious » claims that the judges of the High Court and the Court of Appeal wrongly ruled that both the description and the claim should be interpreted as not including the recombination process of rCT protein produced from the bacterium *R.erythropolis*.

Indeed, to say, as the High Court and the Court of Appeal did, that a person skilled in the art would interpret the description and claim as not including the recombination process applied to rCT protein produced from the bacterium *R.erythropolis*, would be equivalent to being ignorant of the scope of the functional claims and the theory of equivalents.

Recalling that article 27b sets out that “the patent does not disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art”.

On the one hand, the description is clear and precise enough to be understood by a person skilled in the art.

In fact, reading the patent application, this application is obviously dealing with the question of combination of the bacterium *E.coli* and the protein with respect to the described scientific processes.

The description is sufficiently clear and precise so as to be understood by a person of the art. While reading the criteria-demands, of the patent, it is evident that the question is that of the combining of the *E.Coli* bacteria and the protein according to the scientific processes described.

One can not revoke the patent on the ground of article 27b as the description is complete.

On the other hand, the description is sufficient as it is still general.

Legal precedent at the European Patent Office [**bundle doc 9**] is constant in considering that *"a claim can generally define a characteristic of the invention by indicating its function, even when the description gives only one example of the application of this characteristic, if a person skilled in the art can recognise that other means can be used for the same function"*. (Ciba Geigy case where the possibility of resorting to functional claims was recognised; the solution has been constant since then [**bundle doc 10 and 11**]

In truth, the description of the patent concerns only the bacterium *E. Coli*.

Therefore, one could easily imagine that a bacterium which has the same abilities can be used to produce the same protein.

It is then legitimate to claim that the description and claim of the patent filed by "Ingenious" gives only one example of the application that could be made of his invention : In this case it is the use of the bacterium *E. coli*.

This in no way excludes the possibility that there are other ways of applying the invention, including the bacterium *R.erythropolis*; this use therefore enters into the scope of the protection conferred by the patent.

Consequently, it must be accepted that, contrary to what previous judges have said, a person skilled in the art would be able to interpret the description as itself interpreting a functional claim and that, in effect, this implicitly includes other processes and use of the bacterium *R.erythropolis* is part of this.

Moreover, article 24(4) establishes that the description and the claim have to be interpreted while taking into account all the possible equivalents.

We will see the theory of equivalents later.

Now that we have established the patent is valid, let's consider EHC's infringement on it.

B. Contrefaçon :

Based upon the passing-off, the lower court judged that there was no infringement.

The article 3 of the Code of Erewhon reiterates the conditions of forgery. According to a ruling by the final court of appeal on January 4th 1994⁵ [**Bundle 12**], a forgery has been committed only when there are similarities between the essential elements of the patented object, and of that being used by the defendant. The forgery may then be realized through the exploitation of a similar equivalent;

Yet we cannot deny the obvious resemblance between my clients patented invention and the activities of the EHC. The two processes involve the same method of combining the protein and bacteria, the only difference being the type of bacteria.

This difference has brought about a change of raw materials . However this difference has never permitted the identification of a invention in itself.

Thus French law courts have again confirmed that a differing subject matter does not qualify an inventive step⁶ [**your Lordship can see again Bundle doc 6, 7 and 8**]: It can be thus unequivocally stated that by themselves EHC have not pursued their own process but rather that of my client.

Even if the description made in my client's application does not deal with the same bacterium used by EHC, the resemblance of these two processes is obvious and constitutes a passing-off by EHC.

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6 On en avait déjà parlé

Furthermore article 24(4) of the Code states clearly that the description and claim must be interpreted taking all possible equivalents into account.

The doctrine **[Bundle doc 13]** defines the theory of equivalents concerning patents as being able to *"cover several variants of execution of the invention, when it simply concerns means used routinely in industry"*.

The French Supreme Court of appeal **[Bundle doc 14]** sanctions infringement by equivalence. Indeed, according to this Court, infringement does not require the patented invention to be reproduced identically, reproduction in an equivalent form will be sanctioned just as much. The penalty therefore concerns the identity of the function between the litigious object and the patented object *"if it is true that the incriminated device involves particular means which are not identical to those defined by the patent [...], these means are equivalent and fulfil the same technical function to obtain the same result ;*

And **[Bundle doc 15]**, *When a product is obtained directly by a process equivalent to the process which is the subject of the patent, the court of appeal had legal grounds for deciding that these companies had committed acts of infringement"*

In our particular case, it must be considered, in support of "Ingenious's" request, that the use of the bacterium *R.erythropolis* by "EHC" constitutes routine use, since it is not contested that the bacterium is not new and that this use aims to reproduce in an equivalent form, the synthetic protein produced and patented by "Ingenious".

Consequently, the use by "EHC" of the bacterium *R.erythropolis* to produce its own synthetic protein does constitute infringement, under the heading of article 3 of the Code, and must be penalised by the judges of Erewhon Supreme Court.