

*EHC*

*responding to the appeal and cross-appealing*

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

If you agree, we are going 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 conduct can't be patentable and is not in the scope of claim one properly construed. Ingenious' claim should be revoked.

Intellectual property laws grant us an exclusive right on the invention as soon as you can demonstrate a valid document of title. Without it, neither infringement, nor claim is possible. And the question is to inspect the patent's validity ; I mean the patent which has been granted by Ingenious.

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So,

Firstly, I will submit that the invention is not patentable because of its nature, its non novelty, its contradiction with the *public policy and the inventive step (under the article 27a*

Then, Dimitri will submit that the patent was granted because there is no passing of n light of the article 27b

## **I. Preliminary information on the infringement suit**

First it's important to highlight the Appeal Court sustained the claim that infringement is not characterised.

We contest the existence of infringement, judging that the "Ingenious" patent is not valid in the sense of articles 3 and 27 of the Code.

The patent infringement is also envisaged by the French IP code in the articles L. 615 and following. I quote :

“All infringement on rights of the patent's holder is a passing off”.

## **II. On the patentability of the invention process**

So, we can find four cumulative conditions (the nature of the discovery, the novelty, the public policy and the inventive step) which must necessary be raised to consider the invention as patentable. We are going to demonstrate that in this particular case, none of these conditions is raised.

### **A. On the discovery**

About the discovery, the Erehon Appeal Court wrongfully sustained the fact that the patent

claim does not concern a discovery but an invention.

According to article 27(a) of the Code, a patent can be revoked by the judge if it does not meet the requirements of articles 20 to 23. Similarly, article 21 notes the obligation of an invention.

We can also find the same disposition in the French IP code (article L. 611-10) Are not considered as inventions [in particular] discoveries.

The Geneva Treaty [BUNDLE n ] defines a discovery as *"the recognition of phenomena, properties or laws of the material universe which have not previously been recognised and which can be verified"*. The French reputable jurist, Professor Mousseron [BUNDLE n ] completes this, saying that *"a discovery is distinguished by the fact that it is a perception through observation of a natural phenomenon which existed before any human intervention whereas an invention is characterised by the fact that it is the deliberate coordination by man of material resources"*<sup>2</sup>.

French legal precedent [BUNDLE n ] has already passed judgement on the question. Thus, the Paris Court of Appeal stated that *a natural product, no matter how interesting its discovery may be and how useful it may be to industry, cannot be the subject of a patent except through an industrial method of application or new industrial processes*<sup>3</sup>.

It is clear that the subject of the patent in question satisfies the definition of a discovery. Indeed, CT protein is produced naturally by the human body. The patent therefore consists of using a human gene sequence in order to reproduce it. However, this gene exists in nature without any human intervention.

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1 Article 1.1.1 of the Geneva Treaty.

2 Jean-Marc Mousseron, *Traité des Brevets*, vol. 1 : l'obtention des brevets, Litec, 1984.

3 Paris Court of Appeal, 22 June 1922.

Therefore, since it is a discovery and so the condition is not characterised, the patent must be revoked on the grounds of articles 21 and 27(a).

### **B. On *Ordre public***

We contest the view of the Court of Appeal which states, wrongfully in our opinion, that the patent does not contradict the *ordre public* recalled in article 22.

The French IP code brings the patent getting to the condition of the respect of the public policy. The article L. 611-17 states that are not patentable I quote “Inventions, commercial exploitation of which would be in contradiction with the human dignity, the public policy or the public morality”.

The EPO [ **BUNDLE n and n** ] defines *ordre public* as covering “*the protection of public interests and the physical integrity of individuals as members of society. Consequently, inventions, the implementation of which risks disturbing public peace or social order (...) or which may cause severe damage to the environment, must be excluded from patentability*<sup>4</sup>”.

It is therefore the role of the judge to conclude that this patent contradicts *ordre public* because it concerns a human gene, and is therefore akin to appropriation of humanity. Similarly, the combination of protein and bacterium must be considered to be within the context of genetic mutations, concerning which several decisions have already remarked on the disturbance of nature<sup>5</sup>. Therefore, on these grounds, the patent must be revoked.

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4 EPO, 1995, Plant Genetics System affair.

5 EPO, 1992, Harvard oncogenic Mouse case.

The third conditions which is also lacking is the novelty of the invention.

### **C. On the novelty of the invention**

Although the request made by "Ingenious" was rejected by lower jurisdictions, the judges nevertheless considered that the invention was new. However, with respect to articles 20 and 23, we considers that this condition of novelty is not met. It claims that the two proteins are identical.

The condition of novelty is envisaged by the French IP code in the articles L. 611-11 : “ Is considered as new, the invention which is not known by the state of the arts”. It has to be determined in comparison with all of what has been divulged to the public.

Concerning the divulgation we consider that the claimant only divulged it on 17 September 2005, the date on which the claim was filed with the Patent office, whereas niCT protein has clearly been available to the public since 1982.

The State of the art states that there must be no prior art relative to the patent. Article 54 §2 of the European Patent Agreement<sup>6</sup> [BUNDLE n ] defines prior art as *"an assembly consisting of everything which was made available to the public before the date on which the patent claim was filed, in a written or oral description, usage or any other means"*.

The last condition to consider is the inventive step which is also lacking.

### **D. On the inventive step**

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.

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<sup>6</sup> Article 54 §2 of the European Patent Agreement

The French IP code provides the same condition in the articles 611 [dash] 10 and 611-14 which respectively correspond to articles 52 (1) and 56 EPA.

It envisages that this condition is fulfilled as far as the invention is not logically the result of the state of the art to a specialist.

Although once more the courts had ruled in favour of " Ingenious", and we contest the applicant's inventive step.

In fact, we strongly contested the existence of an inventive step, claiming that the recombination process was known before 17 September 2005 and that "Ingenious" simply combined this technique with the discovery of information about the gene which produces CT protein.

It is relevant to consider legal precedent to appreciate the state of the art. For instance two French courts have ruled that an invention can't be patented either when the invention is in itself the necessary result of a rational research <sup>7</sup> [BUNDLE n 7 ], or when it is "considered as a natural solution regarding the required result"<sup>8</sup>[BUNDLE n 8 ]. In our particular case, it clearly appears that the invention is obvious and so could not be patented.

Furthermore "Ingenious's" activity consisted of performing simple operations in execution of previous techniques.

Dr Pollack's work is considerable and undeniable, but only with respect to isolating the gene and not the recombination process.

Indeed, this condition is met when the invention does not obviously result from prior art

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<sup>7</sup> CA PARIS 22 janvier 1980, 260, III, p.123

<sup>8</sup> CA PARIS 13 novembre 2002, PIBD 2003 n°762, III, p. 535.

from the point of view of a person skilled in the art.

Another French legal precedent [ **BUNDLE n 9** ] defines a person skilled in the art as being "someone who has normal knowledge of the technique in question and, using his/her professional knowledge only, is capable of developing the solution to the problem which the invention is held to solve<sup>9</sup>".

For us , since the process was already known to person skilled in the art it is even a routine operation. It is the subject of the process which was previously unknown, which goes back to the idea that this is a discovery and not an invention.

But, If you're extraordinary considering that this invention is patentable, I would like to call your attention to the fact that the patent should be revoked on the ground of article 27(b).

### **III. Request for revocation of the patent on the grounds of article 27(b)**

We state that the bacterium *R.erythropolis* is not described or claimed.

Indeed, there could not be an implicit claim on the grounds of a supposed theory of equivalents. It is precisely because "Ingenious" has suddenly realised that his claim and its description are manifestly incomplete, that he is trying in vain to complete it. It is therefore undeniable that "EHC" cannot be condemned on the grounds of article 3 of the said Code and that the patent obtained by "Ingenious" must be revoked.

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<sup>9</sup> Chambre commerciale de la Cour de cassation (French Supreme Court, Commercial Court),17 October 1995,"Robert Bosch vs Etablissements Guillet".

As it was very well demonstrated in the two lower courts which ruled on this case, it seems obvious that the description and claim targeted only the bacterium *E.coli* and that the process resulting from use of this bacterium was not mentioned. This absence must be interpreted by a professional as a possibility for "EHC" to exploit rCT protein obtained using the bacterium *R.erythropolis*.

Since it then concerns functional claims, "Ingenious" is wrong to pretend that the description and claim implicitly include the process of recombination between CT protein and the bacterium *R.erythropolis*.

In fact, it was shown in the order *Biogen Inc v. Medeva*<sup>10</sup>, [BUNDLE n 10 ] that if the claims include several discrete methods or products, as "Ingenious" claims in this case, the patent must **demonstrate that the invention works for each of them.**

Since this demonstration is clearly absent, it must be considered that "Ingenious" did not want to target the process involving the bacterium *R.erythropolis*, now used legally by "EHC".

Furthermore, the description and claim must be considered to be inadequate to exploit the patent. "EHC" therefore requests revocation of the patent on the grounds of article 27(b).

Indeed, according to constant legal precedent of the Supreme court of appeal [BUNDLE n 11 ] and European patent office [BUNDLE n 12 ], the description is inadequate when a person skilled in the art is "required, in reality, to make the inventor work"<sup>11</sup> or has to exert excessive effort in order to produce the invention<sup>12</sup>.

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10 *Biogen Inc v. Medeva*, House of Lords, 31 October 1996.

11 French Supreme Court, Commercial Court, 8 July 1981, *PIBD* 1981.III.236, *ANN. Propr. Ind.* 1982.61.3.

12 EPO. Dec.T226/85 17 March 1987, *JO E\** 1998 p. 336.

It also appears that, concerning biotechnological inventions, the description can only generally be considered to be complete if a sample of the organic material itself has been filed with an accredited organization. This rule, which mitigates the impossibility of describing in writing certain materials of biological origin used within the context of an invention, was included in the Budapest Convention<sup>13</sup> concerning patents on microorganisms, which has been applicable by right in the United Kingdom since 29 December 1980. **[BUNDLE n 13 ]**

This filing, which could have constituted an accurate description of the invention patented by "Ingenious", clearly did not.

This constitutes a further argument for considering the description to be incomplete and therefore revoking the patent henceforth.

In a nutshell, we would ask you to consider all the arguments we've been developping to conclude that the infringement suit against our client has to fail.

Indeed, regarding we said at the beginning, there couldn't be any passing off on an object which is not protected by Intellectual Property Law. Just remember that the protection established by article 2(c) of Erehwon IP Code can only be applicated to a patentable invention and which has been rightly patented.

We did our best to prove that, on the hand, the protein discovered by the appellant is not patentable, and that, on the other hand, if you ever consider it is, the patent registered by Ingenious has to be revoked.

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<sup>13</sup> Budapest Convention of 28 April 1977 on international recognition of filing microorganisms for the purpose of obtaining a patent .