Genelabs Diagnostics Pte Ltd v Institut Pasteur and Another
[2000] SGCA 60

Case Number : CA 14/2000

Decision Date : 02 November 2000

Tribunal/Court : Court of Appeal

Coram : Chao Hick Tin JA; L P Thean JA; Yong Pung How CJ

Counsel Name(s) : Tan Tee Jim SC and Jason Chan (Allen & Gledhill) for the appellants; Tony Yeo, Gerald Koh and Celeste Ang (Drew & Napier) for the respondents

Parties : Genelabs Diagnostics Pte Ltd — Institut Pasteur; Another

Patents and Inventions – Novelty – Whether prior art documents should be read collectively or individually – Whether prior art anticipated invention – Whether prior art disclosed existence of HIV-2 – ss 13(1), 14(1 & 14(2) Patents Act (Cap 221)

Patents and Inventions – Inventive step – State of art at priority date from mantle of person skilled in art – Whether trial judge had sufficient regard to state of art – s 15 Patents Act (Cap 221)

Patents and Inventions – Sufficiency of disclosure – Whether specification enabled invention to be understood and carried into effect by person skilled in art – Whether insufficient disclosure because immuno-reactive portions of amino acid sequence not revealed – s 80(1)(c) Patents Act (Cap 221)

Patents and Inventions – Infringement – Whether relevant claims of patent infringed -Whether addition of five amino acids in test kit to 18mer a material difference – Whether process used by test kit entailed process which fell within claim of patent

Equity – Defences – Acquiescence – Whether party stood by as to induce another to commit the act – Whether there was change of position in reliance on acquiescence

(delivering the judgment of the court): This is an appeal against the decision of Tay Yong Kwang JC where he held that the respondents` patent in respect of, inter alia, the Human Immunodeficiency Virus-2 (`HIV-2`) and an antigen of HIV-2 of a stated amino acid sequence, is valid, and that the appellants had infringed that patent when they manufactured and sold their diagnostic kits for the HIV-2.

The facts

The first respondents are a private, non-profit making foundation in France. They are the proprietor of European patent No 0239425, which covers, inter alia, the HIV-2, a retrovirus capable of causing acquired immune deficiency syndrome (`AIDS`) in man. The patent relates to a discovery made by Professor Luc Montagnier and his team at the premises of the first respondents in 1986. The European patent application was filed on 22 January 1987 and granted on 2 November 1989, and claims priority from its French application, which was filed on 22 January 1986 (`the priority date`).

One of the countries designated in the European Patents Office (`EPO`) filing was the United Kingdom. The patent was subsequently re-registered in Singapore under the Registration of United Kingdom Patents Act on 15 January 1993 under No 9190285-8.

The claims of the patent cover the following aspects:

Claims 1 to 9	-	the HIV-2 and variants thereof;

Claims 10 to 19	-	the antigens of HIV-2;
Claims 20 to 32	-	the compositions for the in vitro detections of HIV-2 antibodies;
Claims 33 to 37	-	the processes for the in vitro detection of, inter alia, HIV-2 antibodies;
Claims 38 to 40	-	diagnostic kits for the in vitro detection of inter alia, HIV-2 antibodies.

The second respondents are a company incorporated in France. The first and second respondents entered into a collaboration agreement on 26 March 1981, which was renewed on 11 July 1990 (`collaboration agreement`). Under the terms of the collaboration agreement, the second respondents are the exclusive licensee of the first respondents` patent.

The appellants are a local subsidiary of an American biopharmaceutical company, Genelabs Technology Inc. They make and sell, inter alia, diagnostic kits that utilise a laboratory technique known as Western Blot to detect HIV-2. Their kits are known as `Genelabs Diagnostics HIV-2 Western Blot 1.2` (`Blot 1.2`) and `Genelabs Diagnostics HIV-2 Western Blot 2.2` (`Blot 2.2`).

The Western Blot is a variation of a procedure devised in the 1970s to detect deoxyribonucleic acid (`DNA`) fragments, known as Southern Blot. When the technique was adapted to detect ribonucleic acid (`RNA`) fragments, it was called Northern Blot. When the technique was subsequently adapted to detect proteins, it was termed Western Blot.

In a Western Blot analysis, HIV proteins are separated by a standard laboratory technique known as gel electrophoresis. This technique makes use of an electric current to separate the proteins. The smaller proteins would move through the gel faster than the larger proteins, thereby allowing for separation according to size. The separated proteins, such as gp41 and gp120, are then transferred to a strip of special nitrocellulose paper paper by blotting the paper to the gel. Each nitrocellulose strip would thus contained several discrete proteins of HIV.

The testing process operates on the principle of antigen-antibody reaction. In very basic terms, antibodies are formed and released by the body in response to the introduction of antigens into the body. An antigen is a substance foreign to the body that stimulates the production of antibodies. The antibody is a protein created to neutralise the harmful effects of the antigen. It is highly specific for the antigen that elicited its production and will interact only with that antigen.

During testing, serum from a patient is applied directly to the antigenic protein bands located on the nitrocellulose strips. If antibodies are present in the serum, they will bind to their complementary antigenic determinant, forming an immunological conjugate, also called immunological complex. Thus, a HIV gp120 antibody would bind to the HIV gp120 antigenic determinant. A colouring agent is used to detect if an antibody has complexed with any of the banded HIV antigenic proteins located on the nitrocellulose strip. The presence of such colour reaction would indicate that the patient has HIV.

Evidence was led that in about 1996, the respondents became aware that HIV-2 test kits were manufactured and sold by the appellants. In April 1998, the respondents carried out investigations that culminated in trap purchases of the appellants` Blot 1.2 and Blot 2.2 diagnostic kits in July 1998. After testing the diagnostic kits for possible infringement of the patent, the respondents decided to

commence action against the appellants, asserting that Blot 1.2 infringed claims 12, 13, 20, 22, 24, 33, 34, 35, 38 and 39 of the patent and that Blot 2.2 infringed claims 19, 20, 33, 34, 35, 38 and 39 of the patent.

In defence, the appellants contended that the patent was not valid. They centred their defence on the lack of novelty and inventive steps in claims 19 and 33. These claims cover:

> *Claim 19*
>
> *Antigens having the following amino acid sequence or a part of said sequence, providing that it raises a specific immunological reaction with the antibodies against a HIV-2 retrovirus, according to any one of claims 1 to 9, especially when this antigen is contacted with the serum of a patient infected with HIV-2 ...*
>
> *Claim 33*
>
> *Process for the in vitro detection of the presence of antibodies, induced in man infected with a human HIV-2 retrovirus, in a human biological sample such as a serum and more particularly for the in vitro diagnosis of a potential or existing LAS or AIDS due to such a retrovirus and obtained from the person being diagnosed, characterised in that this biological sample is contacted with an antigen recognised by an antibody induced in the infected man, by a human HIV-2 retrovirus as defined in claims 1 to 9 in conditions authorising the formation of an immunological complex between this antigen and the said antibody and in that the possibly immunological conjugate formed between this antibody and antigen used is detected.*

The appellants also argued that there was insufficient disclosure in the patent and that the defence of acquiescence applied by virtue of the respondents` unreasonable delay in pursuing relief.

Decision below

The trial judge held that the patent is valid. He found that there was novelty in claim 19 of the patent, as the prior art documents, either individually or collectively, did not clearly and unmistakeably disclose any antigen having the amino sequence or part thereof described in claim 19. It was not logical to suggest that the prior art revealed the function of detecting a virus which was then unknown. Claim 33 is concerned with the process to detect the new virus. It would follow that the process is new when it provides the means to detect a new virus.

The trial judge found that the inventive step requirement was satisfied in respect of claim 19 as it was not obvious to invent an antigen with the specified sequence to detect an as yet unknown virus. The inventiveness manifested in claim 33 was in the recognition that a new virus was responsible for causing AIDS in West Africa and providing the means to detect it by using an antigen.

The trial judge also found that the appellants` diagnostic kits infringed the claims of the patent as the sequence of 18 amino acids (`18mer`) used by the appellants in their diagnostic kits was a highly immuno-reactive portion of the amino acid sequence set out in claim 19, and while the diagnostic kits also used five other amino acids, the latter did not alter the immuno-reactive character of the 18mer

but served only as a fixing and stabilising agent for the 18mer on the nitrocellulose strip.

Issues

Before us the appellants canvassed the same issues which were raised in the court below, namely:

(i) were the inventions, as disclosed in claim 19 and 33 of the patent, novel;

(ii) did the inventions, as disclosed in claim 19 and 33 of the patent, involve any inventive steps;

(iii) was there sufficient disclosure in claims 19 and 33;

(iv) did the production/sale of the diagnostic kits by the appellants infringe the patent;

(v) was there any delay/acquiescence on the part of the respondents in commencing proceedings against the appellants;

(vi) as the collaboration agreement between the respondents was not registered at the commencement of the action, is the second respondent precluded from recovering damages or seeking an account of profits in view of s 75 of the Patents Act 1994 (hereinafter referred to as `the Act` or `the 1994 Act` as may be appropriate in the context).

From the appellants` case, it is quite clear that the first two issues are their main contentions. Nevertheless, we will consider each of the issues in turn.

Novelty

Under s 13(1) of the Act an invention, to be patentable, must satisfy the following conditions:

(i) the invention is new;

(ii) it involves an inventive step; and

(iii) it is capable of industrial application.

In relation to the present case, it is not in dispute that condition (iii) is satisfied. It is in relation to the first and second conditions that the present case turns.

Section 14(1) of the Act provides that an invention shall be taken to be new if it does not form part of the state of the art. Subsection (2) elaborates on the concept of the `state of the art` as follows:

> *The state of the art in the case of an invention shall be taken to comprise all matter (whether a product, a process, information about either, or anything else) which has at any time before the priority date of that invention been made available to the public (whether in Singapore or elsewhere) by written or oral description, by use or in any other way.*

In relation to this case, the priority date is 22 January 1986, that being the date on which the

subject patent was applied for in France.

The first requirement raises the question of novelty and the contention of the appellants is that the invention had been anticipated by prior disclosure in four prior art publications. A leading authority which dealt with the question of prior disclosure is **General Tire & Rubber Co v Firestone Tyre & Rubber Co Ltd & Ors** [1972] RPC 457 and there the Court of Appeal stated (at p 485):

> *... the question whether the patentee`s claim is new for the purposes of s 32(1)(e) falls to be decided as a question of fact.* ***If the prior inventor`s publication contains a clear description of, or clear instructions to do or make, something that would infringe the patentee`s claim if carried out after the grant of the patentee`s patent, the patentee`s claim will have been shown to lack the necessary novelty, that is to say, it will have been anticipated****. The prior inventor, however, and the patentee may have approached the same device from different starting points and may for this reason, or it may be for other reasons, have so described their devices that it cannot be immediately discerned from a reading of the language which they have respectively used that they have discovered in truth the same device; but if carrying out the directions contained in the prior inventor`s publication will inevitably result in something being made or done which, if the patentee`s patent were valid, would constitute an infringement of the patentee`s claim, this circumstance demonstrates that the patentee`s claim has in fact been anticipated.*
>
> *If, on the other hand, the prior publication contains a direction which is capable of being carried out in a manner which would infringe the patentee`s claim, but would be at least as likely to be carried out in a way which would not do so, the patentee`s claim will not have been anticipated, although it may fail on the ground of obviousness.* ***To anticipate the patentee`s claim the prior publication must contain clear and unmistakeable directions to do what the patentee claims to have invented: Flour Oxidizing Co Ltd v Carr & Co Ltd*** *((1908) 25 RPC 428 at 457, line 34, approved in* ***BTH Co Ltd v Metropolitan Vickers Electrical Co Ltd*** *[1928] 45 RPC 1 at 24, line 1).* ***A signpost, however clear, upon the road to the patentee`s invention will not suffice. The prior inventor must be clearly shown to have planted his flag at the precise destination before the patentee****. [Emphasis added.]*

In the recent case, **Merrell Dow Pharmaceuticals Inc v HN Norton & Co** [1996] RPC 76, the plaintiffs discovered an anti-histamine drug called terfenadine for use by people who suffered from hay-fever and similar allergies. Unlike other similar drugs, this drug did not have the side effect of making the person drowsy. The plaintiffs` exclusive right to terfenadine expired in December 1992. Other drug manufacturers thus embarked on making and marketing terfenadine. However, the plaintiffs claimed that their monopoly in terfenadine continued because of a later patent. This later patent came about because their research showed that terfenadine was absorbed in the small intestines and was then 99.5% metabolised in the liver. This was why it had no side effects. They analysed the chemical composition of the acid metabolite formed in the liver. No one had identified that compound before. So they patented the acid metabolite. The plaintiffs` claim to a later patent was in respect of acid metabolite as a product. The defendants contended that while the acid metabolite as a chemical compound had not been previously identified, its manufacture in the body by the ingestion of terfenadine was nevertheless part of the state of the art. This submission was upheld by the House, which essentially approved the approach taken in ***General Tire*** . Lord Hoffmann, who delivered the only judgment of the House, explained the point by way of an analogy (at p 88):

There is an infinite variety of descriptions under which the same thing may be known. Things may be described according to what they look like, how they are made, what they do and in many other ways. Under what description must it be known in order to justify the statement that one knows that it exists? This depends entirely upon the purpose for which the question is being asked. Let me elaborate upon an example which was mentioned in argument. The Amazonian Indians have been known for centuries that cinchona bark can be used to treat malarial and other fevers. They used it in the form of powdered bark. In 1820, French scientists discovered that the active ingredient, an alkaloid called quinine, could be extracted and used more effectively in the form of sulphate of quinine. In 1944, the structure of the alkaloid molecule (C20H24N2O2) was discovered. This meant that the substance could be synthesised.

...

Imagine a scientist telling an Amazonian Indian about the discoveries of 1820 and 1944. He says: `We have found that the reason why the bark is good for fevers is that it contains an alkaloid with a rather complicated chemical structure which reacts with the red corpuscles in the bloodstream. It is called quinine.` The Indian replies: `That is very interesting. In my tribe, we call it the magic spirit of the bark.` Does the Indian know about quinine? My Lords, under the description of a quality of the bark which makes it useful for treating fevers, he obviously does. I do not think it matters that he chooses to label it in animistic rather than chemical terms. He knows that the bark has a quality which makes it good for fever and that is one description of quinine.

...

I recognise that there is a distinction between cinchona bark and terfenadine. The former is a substance occurring in nature and the latter is an artificial product. This might have been relevant if the medicinal qualities of the bark had been unknown and a person who discovered them had tried to patent the bark or the natural alkaloid. But the distinction is not material to the present question, which is essentially an epistemological one: what does it mean to know something, so that it can be part of the state of the art? The quinine example shows that there are descriptions under which something may in a relevant sense be known without anyone being aware of its chemical composition or even that it has an identifiable molecular structure. This proposition is unaffected by whether the substance is natural or artificial.

His Lordship then concluded (at pp 90-91):

In this case, knowledge of the acid metabolite was in my view made available to the public by the terfenadine specification under the description `a part of the chemical reaction in the human body produced by the ingestion of terfenadine and having an anti-histamine effect`. Was this description sufficient to make the product part of the state of the art? For many purposes, obviously not. It would not enable anyone to work the invention in the form of isolating or synthesising the acid metabolite. But for the purpose of working the invention by making the acid metabolite in the body by ingesting terfenadine, I think it plainly was. It enabled the public to work the invention by making the acid metabolite in their livers. The fact that they would not have been able to describe the chemical reaction in these terms does (not) mean that they were not working the invention. Whether or not a person is working a product

> *invention is an objective fact independent of what he knows or thinks about what he is doing. ... The Amazonian Indian who treats himself with powdered bark for fever is using quinine, even if he thinks that the reason why the treatment is effective is that the tree is favoured by the Gods. The teachings of his traditional medicine contain enough information to enable him to do exactly what a scientist in the forest would have done if he wanted to treat a fever but had no supplies of quinine sulphate.*
>
> ...
>
> *Anticipation by disclosure, on the other hand, relies upon the communication to the public of information which enables it to do an act having the inevitable consequence of making the acid metabolite. The terfenadine specification teaches that the ingestion of terfenadine will produce a chemical reaction in the body and for the purpose of working the invention in this form, this is a sufficient description of the making of the acid metabolite. Under the description, the acid metabolite was part of the state of the art.*

A pertinent EPO case relied upon by the House of Lords in ***Merrell Dow*** was **Availability to the Public Decision G01/92** [1993] EPOR 241 where the Enlarged Board of Appeal held that the composition or internal structure of a product becomes part of the state of the art if it is possible for a skilled person to discover it and reproduce it without undue burden.

In **Merck & Co Inc v Pharmaforte Singapore Pte Ltd** [2000] 3 SLR 717 , this court, having considered the authorities, concluded that for a prior publication to anticipate the patent it must be established that following the teachings in the prior publication would inevitably lead to the invention covered by the patent. The prior disclosure must not only identify the subject matter of the claim in the later patent, it must do so in a way that enables the skilled man to make or obtain it, a kind of enabling disclosure.

Finally, we would refer to an early case, **Hills v Evans** [1862] 31 LJ Ch 457 at 463, where Lord Westbury LC set out the test to apply to determine whether the disclosure, contained in a prior document, is such as to invalidate a subsequent invention, in these terms:

> *The antecedent statement must, in order to invalidate the subsequent patent, be such that a person of ordinary knowledge of the subject would at once perceive and understand and be able practically to apply the discovery without the necessity of making further experiments ... the information ... given by the prior publication must, for the purposes of practical utility, be equal to that given by the subsequent patent.*

In this regard, there is a preliminary point which arises for consideration: it is whether the four prior art publications (hereinafter referred to as `the four publications` or individually as `Kanki 1`, `Daniel`, `Kanki 2` and `Barin`) should be read individually or collectively. A nineteenth century case, **Von Heyden v Neustadt** [1880] 50 LJ Ch 126, decided that as a general rule prior art documents should not be read collectively but individually, to determine what information each contained. In that case, the defendants put in evidence a mass of materials, extracted from a large number of publications, to show anticipation. James LJ, delivering the judgment of the court, said (at p 128):

> *We are of opinion, that if it requires this mosaic of extracts from annals and treatises, spread over a series of years, to prove the defendants` contention, that contention stands thereby self-condemned.*
>
> *...*
>
> *And if it could even be shown that a patentee had made his discovery of a consecutive process by studying, collating and applying a number of facts discriminated in the pages of such works, his diligent study of such works would as much entitle him to the character of an inventor as the diligent study of the works of nature would do.*

An exception to this rule would appear to be the case where a later document referred to an earlier document or where a series of papers, which formed a series of disclosures, do refer to each other: **Sharpe & Dohme Inc v Boots Pure Drug Co Ltd** [1927] 44 RPC 367.

Of course, difficult situations can arise where a later document only refers to an aspect of a prior document. Would one therefore be justified to read the entire earlier document with the later document as if they were one or does one confine such reading to only that part or those parts of the earlier document which are referred to in the later document? As a matter of logic, it seems to us that only that part or those parts of the earlier document which are referred to in the later document should be so read. To go beyond that would be to read into the later document information which played no part in the thesis advanced therein. That would be inconsistent with the general principle that in determining the meaning of a document, regard may be had only to what is stated in the document itself.

We will now turn to consider what were conveyed in the four prior art publications. A brief note should be made in respect of certain nomenclature used in the four publications. All four publications refer to the human AIDS virus as `HTLV-III`. This is the abbreviated term for Human T-Cell Leukemia Virus-III. The human AIDS virus is also referred to at some points as `LAV`. This is the abbreviated term for lymphadenopathy-associated virus.

At the point of these four publications, which were published from 7 June 1985 to 21 December 1985, the viral cause of AIDS had already been identified. This had occurred sometime between 1983 to 1984. There was however some dispute as to who was the first to isolate the AIDS virus and consequently a dispute over who had the right to name the virus. The American team, lead by Professor Richard Gallo, named the virus HTLV-III. The French team, who were lead by Professor Luc Montagnier, named the virus LAV. An international committee subsequently named the virus Human Immunodeficiency Virus, or HIV. After the discovery of a second HIV in 1986, the first HIV was renamed HIV-1 and the second named HIV-2.

In Kanki 2 references are made to `gp160` and `gp120`. These are abbreviated terms for a glycoprotein of a certain molecular weight. Glycoproteins are complexes of sugar and protein. The number refers to the molecular weight of the glycoprotein, in kilodalton. Thus gp160 is a complex of sugar and protein with a molecular weight of about 160 kilodalton.

Both Kanki 1 and Daniel were published on 7 June 1985. Kanki 1 reports the identification of a simian retrovirus, STLV-III, from sick macaques. The key excerpts of Kanki 1 are as follows:

Kanki 1

We report here on the serological identification and characterisation of a new macaque retrovirus that has striking similarities to the human AIDS virus HTLV-III; we therefore refer to it as the simian T-lymphotropic virus of macaques related to HTLV-III (STLV-III) ...

*Although the high molecular weight glycoproteins of HTLV-III are the most immunogenic antigens in exposed humans, sera from STLV-III antibody-positive macaques showed minimal reactivity to these proteins, indicating an apparent one-way, cross-reactivity of antibodies to these glycoproteins, STLV-III may thus be distinct from HTLV-III, at least to the degree of the type-specific immunoreactivity to the **env**-encoded glycoproteins ...*

*[Concluding paragraph] **The availability of a nonhuman primate naturally infected with a virus related to HTLV-III may facilitate studies of the pathogenesis and treatment or prevention of AIDS**. [Emphasis added.]*

Daniel reports on the isolation of a T-Cell tropic retrovirus from sick macaques. The key excerpts of Daniel are as follows:

Daniel

Abstract. The isolation of a T-Cell tropic retrovirus from three immunodeficient macaques and one macaque with lymphoma is described. The morphology, growth characteristics, and antigenic properties of this virus indicate that it is related to the causative agent of acquired immune deficiency syndrome in humans (HTLV-III or LAV). This virus is referred to as simian T-lymphotropic virus type III (STLV-III) of macaques ...

*[Concluding paragraph] **Studies of the pathogenesis of AIDS as well as the development of an effective vaccine would be aided if HTLV-III had the ability to infect and cause disease in a laboratory animal. However attempts to infect nonhuman primates other than chimpanzees have generally been unsuccessful**. Because of the endangered status of chimpanzees, their use for this purpose will probably be limited. **If STLV-III is indeed pathogenic in macaques, useful approaches to the development and testing of a vaccine for AIDS may emerge**. [Emphasis added.]*

Kanki 2 was published on 22 November 1985. It sets out the discovery of a HIV related retrovirus in the African green monkeys. The key excerpts from Kanki 2 are as follows:

Kanki 2

Thus, it appears that the high molecular weight glycoproteins of this virus are the most immunogenic species in infected monkeys. A similar observation was made in the human system where the env-encoded gp160 and gp120 of HTLV-III/LAV are the most immunogenic proteins in people exposed to the human virus. ...

> *These data indicate that healthy African Green monkeys are infected with a retrovirus closely related to HTLV-III, designated STLV-IIIAGM ...*
>
> *The major STLV-IIIAGM viral proteins are similar in molecular weight to the major **gag**- and **env**-encoded proteins of HTLV-III/LAV. Like the STLV-IIIMAC viral proteins they are recognised by reference HTLV-III-positive human sera ... As in the case of HTLV-III infected people, the gp160/120 appear to be the best serological markers for infection by these closely related viruses. These proteins therefore represent the most obvious antigen target for serological screening purposes. In addition, serologic cross-reactivity directed to these presumed env-encoded antigens suggests that conserved regions of these proteins should be evaluated as potential immunogenic epitopes for development of a human AIDS vaccine ...*
>
> *[Concluding paragraph] **Understanding the biology of an HTLV-III related virus in this primate species may** help us to understand the specific viral alterations or viral-host interactions that are involved in the pathogenicity of this family of T-lymphotropic retroviruses and perhaps **provide a new approach in the development of an AIDS vaccine**. [Emphasis added.]*

Finally, on 21 December 1985, the last of the four prior art documents, Barin, was published. It essentially reports the following:

> *Barin*
>
> *Summary ... **These results suggest that certain healthy Senegalese people have been exposed to a virus that is more closely related to STLV-III than to HTLV-III**. The existence and study of such virus variants potentially with different pathogenicity may provide important information for the development of an AIDS virus vaccine ...*
>
> *Our study suggests that people in Senegal, where AIDS has not yet been reported, have also been exposed to viruses of the HTLV-III class. However, the virus we found in some healthy prostitutes and surgical impatients is more closely related to STLV-IIIAGM than to reference strains of HTLV-III ...*
>
> *[Concluding paragraph] **Since the STLV-IIIAGM infection has thus far only been described in healthy African monkeys and the related virus in Senegalese people was apparently present in the absence of recognised AIDS, an evaluation of the virology and the immunobiology of these agents in their respective hosts may provide important clues to the development of an AIDS vaccine**. [Emphasis added.]*

The appellants argue that the four publications show that at the priority date:

(i) it was already known that there was in existence a virus, the Simian Immunodeficiency Virus, or SIV, that infected not just simians but also humans;

(ii) that the envelope glycoproteins gp160 and gp120 had been isolated from SIV and the characteristics of these glycoproteins were already known; and

(iii) that the SIV envelope glycoproteins that had been isolated were obvious antigen targets for serological screening purposes.

The appellants seek to further support their argument that there was no novelty in the appellants` invention, by arguing that subsequent studies have shown that:

(i) HIV-2 is in fact the same virus as SIV, that is, HIV-2 is in fact a SIV infection in humans;

(ii) contrary to the respondents` contention, there are no material differences between HIV-2 and SIV; and

(iii) the SIV gp160 and the HIV-2 gp140 are the same.

Consequently, the amino acid sequence of the HIV-2 gp140 and its antigenic effects in respect of the HIV-2 virus, as covered by claim 19, had been anticipated by prior art.

It seems to us that the answer to one assertion made by the appellants is crucial to the question whether there has been anticipation by prior art: has any of the prior art documents shown that SIV had the capacity to infect humans? The answer is no. The prior art documents show that SIV infects simians. Nothing in them indicate that SIV would infect humans with AIDS. It would be seen that Kanki 1 and Daniel reported the isolation of the STLVMAC virus from macaques and Kanki 2 reported the isolation of a variant STLVAGM from African green monkeys.

Barin studied certain Senegalese people and that study showed that while those Senegalese were exposed to a virus that was more closely related to STLV-III than to HTLV-III, the Senegalese remained healthy and exhibited no signs of recognised AIDs. Barin, also having noted from Kanki 2 that STLV-IIIAGM had infected only African monkeys who remained healthy, came to the conclusion that `an evaluation of the virology and the immunobiology of these agents in their respective hosts may provide important clues to the development of an AIDs vaccine.`

Admittedly, and as pointed out by the appellants, there is a latency period between initial infection and onset of the disease and AIDs would take a long time to manifest. Still, it is important to bear in mind what was the message that Barin intended to impart. And that document should be construed as at the date of its publication, and one must exclude in that consideration information subsequently discovered: see **Ore Concentration Co (1905) Ltd v Sulphide Corp Ltd** [1914] 31 RPC 206 at 224. Barin never suggested that the Senegalese people could have contracted AIDS from a virus other than HIV-1 and that they did not show any signs of suffering from AIDS because of a long latency period. We should not seek to impute to Barin a proposition which was never advanced, and which is really an ex post facto rationalisation in the light of later discovery.

What these researchers were studying was why strains of viruses similar to HIV did not cause AIDS in primates or humans. From there, they hoped to develop a vaccine for the HIV virus. There is no question of any of those prior art documents indicating that there was another strain of HIV virus which could infect humans.

The appellants say that there was an imputation that SIV could cause AIDS in humans because Daniel and Kanki 2 had reported that the SIV infects and injures the human HUT-78 cell. The HUT-78 is a cell line developed in 1980. A cell line is a particular type of cell which is used in immunologic research. Normal human cells generally have a finite life span in culture. After a certain period of time, the cells stop dividing. In contrast, normal cells that have undergone transformation, by for example chemical carcinogens or viruses, can be propagated indefinitely in tissue culture. Such cells are

referred to as cell lines.

In the case of HUT-78, the cell line originated with a patient diagnosed with Sezary Syndrome, a type of lymphoid leukemia. It is a cell which has been infected by leukemia and transformed such that it propagates indefinitely, contrary to normal cell behaviour. It was through the use of the HUT-78 cell line that scientists were able to grow the HIV in sufficient mass quantity for diagnosis kits using HIV antigens to become viable. In Daniel and Kanki 2, HUT-78 cell lines were used to culture SIV.

The remarks of Professor Cohen, the respondent`s expert, on this issue, is pertinent. Professor Cohen was referred to a line in Kanki 2 which said that a cytopathic effect was observed in the HUT-78 cell lines after 7 to 28 days of culturing SIVAGM. The cross examination is as follows:

> *Q: Reading the two passages there, do you agree that it was known that SIVs are cytopathic to T4 cells?*
>
> *A: A SIV is demonstrated to be cytopathic in HUT-78 ...*

Professor Cohen`s emphasis was that all that Kanki 2 showed was that SIV was cytopathic to HUT-78, which is a cell line. He did not agree that Kanki 2 showed that SIV was cytopathic to T4 cells, which are the helper T-lymphocyte cells of the body. He went on to observe:

> *Cytopathic-means something harmful to a cell, able to kill a cell. Cellular level. Pathogenic-refers to something inducing a disease in a living animal or man. If a virus that kills a cell in a laboratory, i.e. cytopathic, it does not mean it will also be pathogenic to man.`*

Indeed, if the culturing of SIV in HUT-78 cell lines meant that humans could acquire AIDS from SIV, Kanki 1 and Daniel would have ended with the pronouncement that SIV could cause AIDS in humans, rather than that the study of SIV could lead to the development of an AIDS vaccine. It is also noteworthy that Professor Letvin, who was a co-author of Daniel, did not anywhere in his evidence offer the view that SIV was shown to infect humans merely on the basis of SIV infection of HUT-78 cell lines. Professor Letvin himself had written in an article entitled `In vitro growth characteristics of simian T-lymphotropic virus type II` published in October 1985 that:

> *Abstract ... STLV-III differs from the human AIDs virus [in certain respects] ... and its less striking toxicity for T lymphocytes. These studies provide further characterisation of an agent that will be extremely important in facilitating the development of vaccines and antiviral therapy for AIDS.*

In summary, the four prior art documents relied on by the appellants did not indicate that SIV could infect humans with AIDS. They could not and did not inevitably lead to the discovery of another HIV and the method of detecting it. Instead the prior art documents relied on led away from it, towards a non-pathogenic virus with hopes of developing of a vaccine for HIV-1.

The position here is unlike that of ***Merrell Dow*** . There the House of Lords found that knowledge of the acid metabolite had been made available to the public by the terfenadine specification under the description `a part of the chemical reaction in the human body produced by the ingestion of

terfenadine and having an anti-histamine effect`. This enabled the public to work the invention by making the acid metabolite in their livers. The fact that they were not able to describe the chemical reaction in these terms did not mean that they were not working on the invention. In sharp contrast, not only did the four publications fail to describe a process that involves the HIV-2, they did not even predict its existence.

Therefore, there is no basis for the appellants to argue that the HIV-2 and the antigenic component covered by claim 19 were anticipated by prior art. In relation to the novelty of claim 19 in particular, as at 22 January 1986, there was nothing in the prior art that described the 18mer sequence set out in claim 19.

We, therefore, agree with the following conclusion reached by the trial judge in [para] 191 and 192 of his grounds of decision:

> *... the prior art documents relied on by the defendants, read individually or collectively, do not clearly and unmistakeably disclose any antigen having the amino acid sequence or a part thereof as described in Claim 19. The said Claim also deals with the function of detecting HIV-2. Claims 1 to 9 on the novelty of the HIV-2 have not been impugned. It would therefore be illogical to claim that prior art has already revealed the function of detecting a virus unknown to the prior art.*
>
> *Claim 33 is concerned with a process to detect a new virus. As stated above, if the virus is new or novel, the process to detect it must have the same attribute.`*

In the premises, we hold that the contention of the appellants based on lack of novelty fails.

Inventive step

The second requirement which an invention must fulfil to be patentable is that it involves an inventive step. Section 15 of the Act provides that an invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which formed part of the state of the art. This requirement, which is termed as the question of obviousness, is distinct and separate from novelty. An invention lacks novelty if it is shown that the patent claimed includes within its scope something which has previously been made available to the public. On the other hand, in considering the question of obviousness, it is assumed that the invention is novel and differs in some identifiable respect from the prior art. The question to ask is whether it is obvious and hence did not involve any inventive step to devise a product or process falling within the scope of the claim in question. In ***Molnlycke AB v Procter & Gamble Ltd*** (No 5) [1994] RPC 49, Donald Nicholls VC explained the matter as follows (at p 112).

> *Under the statutory code (which is further confirmed in its completeness by ss 74 and 72) the criterion for deciding whether or not the claimed invention involves an inventive step is wholly objective. It is an objective criterion defined in statutory terms, that is to say whether the step was obvious to a person skilled in the art.*
>
> *...*

> *The statute has laid down what the criterion is to be: it is a qualitative not a quantitative test.*
>
> *...*
>
> *The Act requires the court to make a finding of fact as to what was, at the priority date, included in the state of the art and then to find again as a fact whether, having regard to that state of the art, the alleged inventive step would be obvious to a person skilled in the art.*

As regards the appropriate approach which the court should take in determining the issue of inventive step, this was elucidated earlier by Oliver LJ in **Windsurfing International v Tabur Marine (Great Britain)** [1985] RPC 59 where his Lordship set out a four-step approach, as follows:

> *There are, we think, four steps which require to be taken in answering the jury question. The first is to identify the inventive concept embodied in the patent in suit. Thereafter, the court has to assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and to impute to him what was, at that date, common general knowledge in the art in question. The third step is to identify what, if any, differences exist between the matter cited as being `known or used` and the alleged invention. Finally, the court has to ask itself whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require any degree of invention.*

This four-step approach advocated by Oliver LJ was adopted by this court in the recent case ***Merck v Pharmaforte*** (supra).

The appellants accept that the inventive step which the trial judge found was `the discovery of an antigen having the stated amino acid consequence which was capable of specifically bringing about the solution of a newly discovered problem, ie the HIV-2.` But they argue that the trial judge misunderstood the problem and the solution as he did not pay sufficient regard to the state of the art at the priority date from the mantle of the person skilled in the art. In short, the trial judge did not apply the second step advocated by Oliver LJ in ***Windsurfing International*** correctly.

It seems to us that the very foundation for this argument is based on the assertion that the prior art in hand indicated that SIV was pathogenic to man. Following from that premise, the appellants say that the respondents` contribution was essentially in locating or having access to patients exhibiting outward symptoms of AIDS, but who either could not or were not detected as positive by conventional HIV-1 antibody tests, and that such a contribution does not constitute an inventive step.

In arguing that SIV is pathogenic to man, the appellants rely again on the four prior art publications, Kanki 1, Daniel, Kanki 2 and Barin. As discussed earlier in relation to the question of novelty, none of these prior documents did so suggest. It seems to us that this contention clearly smacks of ex post facto rationalization, based on new discovery made after the publication of the four documents. This thread seems to run through much of the appellants` submission. Even on the appellants` own submission the highest they could go was `there was a possibility to which the scientific community had been alerted to of a new retrovirus.` How could something which was only a possibility be

translated into something `obvious to a person skilled in the art to use routine laboratory methods then available to isolate the SIV strains`?

The appellants seek to latch on to a comment by Professor Cohen where he said `by the end of the race, first plaintiff got there first` to argue that `if it had been so implausible, so impossible to ..., why would there be a competition at all to find the virus which was pathogenic to man?` That remark by Professor Cohen was clearly a general remark in relation to the law governing patent, namely, that the first person who made the invention would get the prize of a patent. The scientists may be working broadly in the same direction or they may not. But we do not think that Professor Cohen was in any way suggesting that Barin and others were, in fact, in the same race, bearing in mind that just a few questions before that remark, Professor Cohen had said `by 19 December 1985, the virus from the first plaintiff had been registered in the depository. Barin was going the wrong way, looking for non-pathogenic virus`.

Thus, we are unable to agree with the appellants` contention that what was invented was obvious and that no inventive step was involved.

Insufficiency

We now turn to the next issue - the question of sufficiency of disclosure. A new patent is invalid if the specification does not disclose the invention with sufficient particularity to enable the invention to be understood and carried into effect by a person skilled in the art: see s 80(1)(c) of the Act.

In **Mentor Corp & Anor v Hollister Inc** [1993] RPC 7, the Court of Appeal held that whether the specification of a patent disclosed the invention clearly enough and completely enough for it to be performed by a person skilled in the art was a question of degree. It would be impossible to lay down any hard and fast rule. In each case the question of sufficiency would be a matter of fact, depending on the nature of the invention and the other circumstances of the case. Lloyd LJ, who delivered the judgment of the court, explained the point in this manner (at pp 10-11):

> *The question for decision in the present case is whether the specification discloses the invention clearly enough and completely enough for it to be performed by a person skilled in the art. This obviously involves a question of degree. Disclosure of an invention does not have to be complete in every detail, so that anyone, whether skilled or not, can perform it. Since the specification is addressed to the skilled man, it is sufficient if the addressee can understand the invention as described, and can then perform it. In performing the invention the skilled man does not have to be told what is self-evident, or what is part of common general knowledge, that is to say, what is known to persons versed in the art. But then comes the difficulty. How much else may the skilled man be expected to do for himself? Is he to be able to produce what Mr Thorley called a workable prototype of the invention at his first attempt? Or may he be required to carry out further research or at least make some further enquiries before achieving success? And how does one draw the line between production of the so-called workable prototype and the subsequent development or `optimisation` of the commercial product?*
>
> *...*
>
> *In determining the required degree of clarity and completeness it is plainly impossible to lay down any precise rule.*

...

But even if it were possible to lay down a hard and fast rule, I doubt if it would be desirable. For the amount of teaching required in the specification may vary from invention to invention. Where the gist of the invention is an idea, less may be required by way of teaching to produce a workable prototype than where the invention is a new method of manufacture. It is dangerous to generalise.

Claim 19 covers a sequence of 891 amino acids or part thereof, which raise a specific immunological reaction with HIV-2 antibodies. It is common ground that the amino acid sequence in claim 19 is that of the envelope glycoprotein, gp140, of the HIV-2. The appellants argue that there is insufficiency of disclosure because the claim does not disclose which part of the amino acid sequence will raise the specific reaction. The respondent counter that immuno-reactive epitopes, that is, portions of the sequence that react specifically to antibodies of given specificity, can be selected using the amino acid sequence disclosed in claim 19 together with four other pieces of information which were common general knowledge at priority date. These are:

(i) the teaching in the patent that the envelope glycoprotein of HIV-2 is considered the best target antigen in terms of detection efficiency;

(ii) a patent of Professor Richard Gallo in 1984 which revealed that the HIV-1 envelope transmembrane protein p 41 was useful in finding antigens;

(iii) an article by Chang et al in October 1985 that an 82 amino acid peptide from gp41 of HIV-1 successfully detected 99% of HIV-1 patients;

(iv) the disclosure by Geysen et al in July 1984 of the Pepscan as a method of identifying epitopes.

The answer of the appellants` expert, Professor Letvin, disposes of this issue:

Q: ***Once we have the four pieces of information listed, it would be possible for a skilled man to find the immuno-dominant antigens in a virus once the virus has been sequenced?***

A: ***That`s fine.***

...

Q: Put: Without the sequences revealed in the patent and subsequently published in Guyader, this 18mer used by the defendants would not have been obtained.

A: That is correct. Again, it is an issue of law not science as to whether the definition of a protein of a virus takes precedence over the sequencing of that protein. That is not a scientific question.

Q: ***A skilled man has the knowledge to look for the 18mer once the sequence of the HIV-2 virus was revealed?***

A: ***Yes*** *. [Emphasis added.]*

The contention of the appellants on this issue is that there was insufficient disclosure because the immuno-reactive portions of the 891 amino acid sequence was not disclosed. Such a contention has no credibility in the light of their expert`s agreement that with knowledge of the sequence and the four pieces of common general knowledge, it was possible to get the epitope known as the 18mer.

Was there infringement

The next contention of the appellants is that their diagnostic kits do not infringe the patent. It is clear that to determine whether there is infringement, there must first be determined the scope of the monopoly claimed in the patent. The appellants submit that the trial judge failed to appreciate that claim 19 was drafted rather widely, so much so that it would encompass even SIV antigens, which could not have been intended. They refer to a letter of EPO dated 22 April 1988 wherein the first respondent was advised that:

> *(i) In claims 14 to 17, it would be appropriate to specify the antibodies which can be used to recognise the portions of the sequences claimed, and to* ***exclude any polypeptide or peptide presenting homologies of sequences with those of the known HIV or SIV viruses which are liable to be recognised by the same antibodies*** *. [Emphasis added.]*

In answer to that query, the respondents on 21 June 1988 stated:

> *There is no need to emphasise that nothing of the sort has been contemplated in the previous documents.* ***These do not describe the polypeptides or peptides of an SIV retrovirus*** *corresponding to the definition given in claims 15 to 18. [Emphasis added.]*

In the light of this response, the appellants contend that claim 19 must be restricted to HIV-2 and should not include SIV. In the case of the appellants` Blot 2.2 diagnostic kit, it does not infringe claim 19 because it uses the amino acid sequence of an SIV antigen.

It would be seen that the position taken by the respondents was that the invention opened a novel domain, and that under the usual directions of EPO, the respondents are entitled to broad claims. Moreover, we must also point out, as was done by the respondents in their case, that the complete response of the respondents of 21 June 1988 gives a different picture from that sought to be painted by the appellants. The appellants have misunderstood it. Thus, there is a need for us to quote that part of the letter in full:

> ***We would like to insist on the fact that, as the Examiner recognised in para 2 of the Official Letter, the object of the claims is new and inventive as regards to what relates to the new species of retrovirus having the characteristics stated in the application****.*

***There is no need to emphasise that nothing of the sort has been contemplated in the previous documents. These do not describe the polypeptides or peptides of a SIV retrovirus corresponding to the definition given in claims 15 to 18. This is why it seems to us that the meaning of claims stated above ought not to be limited to the sole sequences of amino acids deriving from the HIV2 retrovirus**.*

***We think that the examiner will subscribe to general formulation of the claims, which is certainly quite general because an invention `which opens up an entirely new area has the right to word claims in more general terms than an invention which only concerns progress made in a known technique`, in the words of Directive C III 6.2**.*

***The present patent application corresponds to a situation of this type, since its object resides in the characterisation of a new species of virus and its various constitutive elements, no characteristics of which proceeds in an obvious from the instructions of documents of the prior art documents as the Examiner has recognised**. [Parts not cited by the appellants are underlined.]*

Therefore, we agree with the respondents that there is nothing in their letter of 21 June 1988 which narrows down their entitlement to only HIV-2 antigens and excluding SIV antigens. In any event, it is not established that the 18mer used by the appellants in their diagnostic kits are that of the SIV. It is acknowledged that the 18mer of the SIV gp160 has one amino acid difference from the 18mer of the HIV-2 gp140. It contains at one point, serine instead of alanine. The appellants argue however that this one amino acid difference is immaterial to the immuno-reactive character of the SIV 18mer. Be that as it may, the point is that the 18mer used is not that of the SIV, but instead corresponds exactly with that of the HIV-2 gp140, as covered by claim 19.

It is settled law that a patent claim should be construed purposively which would accord fair protection to the patentee and yet provide a reasonable degree of certainty for third parties: see **Catnic Components Ltd v Hill & Smith Ltd** [1982] RPC 183. The application of this principle was further elucidated by Hoffman J in **Improver Corp v Remington Consumer Products Ltd** [1990] FSR 181 as follows (at p 188):

The language should be given a `purposive` and not necessarily a literal construction. If the issue was whether a feature embodied in an alleged infringement which fell outside the primary, literal or a contexual meaning of a descriptive word or phrase in the claim (`a variant`) was nevertheless within its language as properly interpreted, the court should ask itself the following three questions:

(1) Does the variant have a material effect upon the way the invention works? If yes, the variant is outside the claim. If no -

(2) Would this (ie the variant had no material effect) have been obvious at the date of publication of the patent to a reader skilled in the art. If no, the variant is outside the claim. If yes -

(3) Would the readers skilled in the art nevertheless have understood from the language of the claim that the patentee intended that strict compliance with

the primary meaning was an essential requirement of the invention. If yes, the variant is outside the claim.

On the other hand, a negative answer to the last question would lead to the conclusion that the patentee was intending the word or phrase to have not a literal but a figurative meaning (the figure being a form of synecdoche or metonymy) denoting a class of things which included the variant and the literal meaning, the latter being perhaps the most perfect, best-known or striking example of the class.

We note that the appellants have only submitted on the alleged infringement of Blot 2.2 diagnostic kit; nothing has been said about Blot 1.2. It would follow from this absence of response that they admit to Blot 1.2 being in infringement, as evidence was led by the respondents that Blot 1.2, as well as Blot 2.2, infringed the patent.

As regards the Blot 2.2 diagnostic kit, it clearly contains the exact same 18mer sequence specified in claim 19 and raises the specific immunological reaction required by claim 19. Thus, the respondents submit that that kit literally infringes claims 19 and 33. Even if consideration should be given to the five extra amino acids, ie 23mer, this is an immaterial variant since those extra acids are no more than a sticking agent, ie a superglue to stick the peptide onto the nitrocellulose strip.

The Blot 2.2 diagnostic kit purports to be a qualitative enzyme immuno-essay for the in vitro detection of, inter alia, antibodies to HIV-2 in human serum or plasma. If HIV-2 antibodies are present in a serum, they will bind with the immobilized antigen on the nitrocellulose strip, thus forming an immunological conjugate, also known as an immunological complex. The immunological conjugate can be detected by using a colouring agent. It seems to us that Blot 2.2 entails a process which falls, in the word of the respondents, `squarely` within claim 33.

The question of infringement is a question of fact. There is clear evidence from the witnesses for the respondents, Professor Cohen and Mr Gallochat, stating that Blot 2.2, as well as Blot 1.2, infringed the patent. The learned trial judge accepted Professor Cohen`s evidence in this respect. There is hardly any sufficient basis for us to interfere with such a finding.

Laches and acquiescence

The basis upon which the appellants raise the defence of acquiescence is that the respondents knew of the appellants` involvement in the production of diagnostic kits for the detection of HIV-2 since December 1993. The appellants say the respondents had such knowledge because of a letter of 23 December 1993 written by the respondents to the appellants` parent company in these terms, following the termination of negotiations to grant a licence to the appellants` parent company:

Referring to our various conversation concerning an HIV2 license agreement, we notify you our decision to put an end to our negotiation regarding PSD territory HIV2 rights for Genelabs or its affiliate Diagnostics Biotechnology.

*As a result, we would like to draw your attention to the fact that if your company **continues**, directly or indirectly through the medium of any affiliate, to manufacture and/or sell products which could infringe our rights, it does so at its own risk, as we are committed to take whatever legal action is necessary*

to protect and enforce our valuable rights. [Emphasis added.]

The appellants place emphasis on the word `continues` in the letter, which suggested that the appellants had already infringed the patent. However, the respondents had, through their witness, explained that this was their standard form warning issued to all potential infringers, and nothing more should not be read into it.

The appellants claim that they have been selling their kits in Europe, including France, since 1987. The appellants further say that they have advertised in numerous publication in which the respondents` licencees had also advertised and therefore, the respondents must have known what the appellants were producing. There were also articles written about their kits. The appellants submit that in the light of all these, it would be unjust to grant to the respondents the relief as the appellants have in the meantime incurred substantial costs on research, development and promotion of their kits.

It should be noted that there is no concrete evidence of such alleged sales of the kits since 1987. As regards the advertisements, their contents were less than specific. The articles too did not say that the product was commercially available and was being sold to the public.

In any event, the crucial question in this regard is whether mere knowledge of infringement and failure to take action to prevent such infringement is sufficient to establish acquiescence. Here the respondents rely on **Farmers Build v Carier Bulk Materials Handling Ltd** [1999] RPC 461 to assert that the answer is in the negative. There, the Court of Appeal approved the following statement of the law set out in 16 ***Halsbury`s Laws of England*** (4th Ed Reissue) para 924.

> *The term acquiescence is ... properly used where a person having a right and seeing another person about to commit, or in the course of committing an act infringing that right, stands by in such a manner as really to induce the person committing the act and who might otherwise have abstained from it, to believe that he consents to its being committed; a person so standing-by cannot afterwards be heard to complain of the act. In that sense the doctrine of acquiescence may be defined as quiescence under such circumstances that assent may reasonably be inferred from it and is no more than an instance of the law of estoppel by words or conduct ...*

The respondents further argue that acquiescence cannot be applied in this case because:

(i) they have always told the appellants that they would sue if the appellants infringed their patent;

(ii) they have warned the appellants and their subsidiaries/affiliates on many occasions that they would sue, and at no time did they indicate that they would not enforce their rights;

(iii) the appellants` witness, Mark Van Asten, admitted that they had never been misled by the respondents` conduct or representation.

We agree that, in the circumstances of this case, the defence of acquiescence can hardly apply. What the appellants have failed to show is that the respondents had `(stood) by in such a manner as really to induce the person committing the act and who might otherwise have abstained from it, to believe that he consents to its being committed.` We cannot see how the appellants could claim that

they genuinely believed that the respondents consented to the infringement. It seems to us that the circumstances suggest that the appellants were quite determined to carry on with what they had been doing irrespective of whether what they did amounted to an infringement of the respondents` patent. To permit the plea of acquiescence in such circumstances would be to permit a defendant to take advantage of its own deliberate wrongdoing. Furthermore, there is no evidence on how the appellants` position had changed on account of the alleged acquiescence. If it were true that the appellants had manufactured and sold their kits in as early as 1987, as they said they had, then the appellants cannot claim that their position had changed post-negotiation. As the respondents` witnesses (Mr Policard) explained, the letter of 23 December 1993 was a standard form letter. It did not mean that the respondents knew that the first appellant was then infringing the patent. The evidence showed that the respondents knew the appellants were planning to infringe. This would follow very much from the fact that the appellants were negotiating for a licence. But that does not amount to knowing that the appellants had already infringed. Furthermore, the respondents had, in fact, warned the appellants not to infringe.

The way the appellants put their case would appear to suggest that there is a duty on a patent proprietor to keep a constant look out for potential infringers. We endorse the view of the trial judge that `there is no duty on the part of the proprietors of patents to scan and survey the market constantly and vigilantly for infringers and to pounce on them immediately when they are sighted`.

A related point in this regard is whether the respondents had been guilty of laches after discovering that the appellants had infringed their patents. There is evidence to suggest that it was only in late 1996 that the respondents discovered that the appellants had manufactured and sold the kits in Singapore on a commercial basis. The present action was commenced against the appellants on 5 October 1998. Bearing in mind that the respondents have no representative office here and had to set up trap-purchases, carry out the necessary analysis and tests, and appoint solicitors and other agents in Singapore, the delay before instituting the action cannot be said to be inordinate. We agree with the trial judge that the respondents did not know of the infringing activities of the appellants until sometime in 1996 and they had proceeded with reasonable despatch thereafter. Furthermore, for reasons indicated earlier, we do not see any prejudice being caused to the appellants on account of the delay in instituting the action.

Non-Registration under s 75

The final point raised by the appellants concerns s 75 of the Act which require, inter alia, that an agreement conferring an exclusive licence upon another be registered within six months of the agreement. To understand the full import of the section we will quote it in extenso:

> *Where by virtue of the transaction, instrument or event to which section 43 applies a person becomes the proprietor or one of the proprietors or an exclusive licensee of a patent and the patent is subsequently infringed, the court or the Registrar shall not award him damages or order that he be given an account of the profits in respect of such a subsequent infringement occurring before the transaction, instrument or event is registered unless -*
>
> *(a) the transaction, instrument or event is registered within the period of 6 months beginning with its date; or*
>
> *(b) the court or the Registrar is satisfied that it was not practicable to register the transaction, instrument or event before the end of that period and that it*

was registered as soon as practicable thereafter.

In the present case, the second respondent had become the exclusive licencees of the patent by virtue of a collaboration agreement dated 26 March 1981 and which agreement was renewed on 11 June 1990. The collaboration agreement was only registered on 1 June 1999, shortly before the commencement of the trial of this action.

The trial judge noted that this point was not pleaded or alluded to in the course of the trial. In any case, he held that s 75 could not have been intended to apply to past transactions such as the document in question here as the Act only came into force on 23 February 1995 (operative date). The previous statute did not contain a similar provision though there was a provision there which required registration of the agreement and the penalty for non-registration was inadmissibility of the document in court as evidence.

The first time this question was raised by the appellants was in their closing submission at the trial. We agree with the respondents` submission that they were prejudiced by the appellants` lateness in bringing up the point. This is because s 75 also provides that the penalty prescribed therein will not apply if `the court is satisfied that it was not practicable to register the transaction ... before the end of (the six month period) and that it was registered as soon as practicable thereafter.` The respondents were deprived of an opportunity to adduce evidence to satisfy the court that s 75 did not apply or, if it did, it had been complied with. Thus, we are of the view that the appellants should be precluded from raising the point.

However, as fairly extensive arguments have been submitted on the applicability of s 75 to this case, we shall briefly indicate our views. The general question that arises for consideration is whether s 75 would apply to `transactions, instruments or events`, which occurred before the operative date. Section 43(3) defines that term to cover, inter alia, assignments, mortgages, licences, devolution upon death or orders of court. The Act also contains a number of transitional provisions. The one relied upon by the appellants is s 116(3) and it reads:

> *Any certificate of registration issued under section 5 of the Registration of United Kingdom Patents Act and is in force immediately before 23rd February 1995, or issued after that date by virtue of subsection (1) or (2) shall continue in force and the patent to which the certificate relates shall be treated for the purposes of this Act as if it were a patent under this Act granted in pursuance of an application made under this Act and the proprietor of the patent shall accordingly have the same rights, remedies, privileges and obligations and subject to the same conditions (including the payment of any fee prescribed under section 36), as the proprietor of a patent under this Act subject to the following modifications:*
>
> *(a) the term of the patent shall date from the date of the patent in the United Kingdom and the patent shall subject to this Act remain in force for 20 years from that date and only so long as the patent has not been revoked in the United Kingdom;*
>
> *(b) such other modifications as may be prescribed.*

The essence of s 116(3) is to say that the proprietor of a patent granted under the previous Act shall be treated as if it were granted under the 1994 Act and the proprietor shall, subject to those specified modifications, enjoy the same rights, remedies, etc, as those of a proprietor of a patent granted under the 1994 Act. It seems to us that s 116(3) has really nothing to do with the assignment of or devolution of a proprietor`s rights to a patent or the grant of an exclusive licence. It would be stretching the sense of s 116(3) too far to argue that the words `obligations and subject to the same conditions` therein could conceivably be interpreted to imply that s 75 would apply to an assignment made or an exclusive licence granted before the operative date. In our opinion, if the Legislature really had that in mind it would have stated so in clearer terms and would also have provided for two different situations which could arise, namely, those cases where on the operative date the six month period had expired and those cases where it had not. We feel justified in taking this view when we see that in the other subsections of s 116 detailed provisions on time frames are set out.

Accordingly, we would be inclined to hold that s 75 has no retrospective operation. It certainly can have no application to a case where the six month period had expired on the operative date. It must be borne in mind that s 75(b) refers to an extension of time to register when `it was not practical to register the transaction, instrument or event.` The word `practical` would suggest that what is required to be done is an act which is `possible` but not `practical`. But where, as in this case, on the operative date, the six month period had long passed, it is absurd to suggest that the non-registration was because it was not `practical`. It was simply not required. Of course, we recognise that the force of this line of argument is less absolute when the `transaction, instrument or event` took place less than six months before the operative date because in such a situation it may be `possible` but not `practical` to effect the registration within the six month period. It could be just one day before the six month period is due to expire or it could be that there were still five months twenty nine days to go. What is the answer to each of these situations is less than clear. Thus, it is really necessary for us to go back to basics. We need to bear in mind two things. First, if the legislature had intended to apply s 75 to `transactions, instruments or events` which occurred before the operative date, why did it not lay down detailed provisions? Second, it is a rule of construction that the legislature must not be deemed to have intended to affect existing rights unless by express provisions. When the Patents Bill was under consideration in Parliament, the Minister for Law informed Parliament that `the repeal of this legislation of UK Patents Act ... will not affect rights already granted under the current law.` Under the previous law the penalty for non-registration was just inadmissibility of the document in court as evidence of title to a patent or licence, `unless the court otherwise directs`. No time limit was prescribed for such registration.

In any event, in so far as this case is concerned, s 75 can have no application whatsoever.

Judgment

In the premises, we agree with the trial judge that the patent is valid and that it is infringed by the appellants` actions. The appeal is accordingly dismissed with costs and with the usual consequential orders.

Outcome:

Appeal dismissed.