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FRENCH REPUBLIC
IN THE NAME OF THE FRENCH PEOPLE

***COUR D'APPEL* OF PARIS**

Division 5 - Chamber 2

DECISION OF 8 OCTOBER 2010

(No. 215, 12 pages)

Docket number: **09/06637**

Decision referred to the *Cour d'Appel*: Judgment of 21 January 2009 - *Tribunal de Grande Instance* of PARIS, 3rd Chamber, 3rd Section - docket No.: 05/10403.

APPELLANT:

INSTITUT PASTEUR
A foundation recognised of public utility,
represented by its legal representative,
having its registered office at 25-28 rue du Docteur Roux 75015 PARIS,

represented by Mr François TEYTAUD, *avoué,*
assisted by Ms Marina COUSTE, attorney-at-law, pleading on behalf of HOWREY LLP, member of the PARIS Bar, court box: L 295.

RESPONDENT:

S.A.S. ABBOTT FRANCE
represented by its President,
having its registered office at 10 rue d'Arcueil 9458 RUNGIS,

represented by S.C.P. MONIN – D'AURIAC DE BRONS, *avoués*,
assisted by Mr SCHERTENLEIB, attorney-at-law, pleading on behalf of HIRSCH, member of the PARIS Bar, court box: W 03.

COMPOSITION OF THE COURT

The case was discussed on 2 July 2010, in public, before the *Cour d'Appel* composed of:

Mr GIRARDET, Presiding Judge,
Ms DARBOIS, Judge,
Ms SAINT SCHROEDER, Judge.

who deliberated.

CLERK: during the trial: Mr NGUYEN.

DECISION:
After hearing both parties,
- pronounced and filed with the clerk's office, after informing the parties pursuant to the provisions of Article 450, second paragraph, of the New French Code of Civil Procedure.
- signed by Mr GIRARDET, Presiding Judge and by Mr NGUYEN, the clerk present when the decision was pronounced.

Institut Pasteur, a private foundation recognised of public utility, developed some research which made it possible to identify the HIV-1/VIH retrovirus which is responsible for AIDS, and to define the means that are specific to the diagnosis thereof in the infected patients.

It is the holder of a number of patents, among which are:

- European patent EP 201 540 B2, entitled "Envelope antigens of lymphadenopathy-associated viruses and their applications"; it aims at isolating a glycoprotein of 110 kiloDaltons (gp 110) expressed by the HIV genome – also called LAV retrovirus. The invention relates in particular to antigens that can be recognised by serums of a human origin containing antibodies against the LAV virus.

- European patent EP 387 914 B1 which is a divisional application based on patent EP 201 540 B2 and claims a purified peptide that can be extracted from a purified glycoprotein from the LAV virus envelope, whose molecular weight is about 110,000 Daltons and whose size does not exceed 200 amino acids.

- European patent EP 211 022 B1 which relates to monoclonal antibodies; this patent is no longer asserted with respect to the infringement;

Institut Pasteur filed, as of 1983, a UK patent No. 8 324 800, covering a kit for detecting the LAV or HIV-1 and did the same with the USPTO.

At the same time, some research was being carried out in the United States, also relating to the isolation of the virus and the characterization thereof as well as to the development of kits for detecting antibodies.

Therefore, a patent application was filed in the United States on 23 April 1984, followed by the granting of a patent under No. 4 520 113 which also relates to detection means.

Following various disputes which opposed Institut Pasteur to the American Department of Health and Human Services, hereinafter referred to as DHHS, and to the National Institute of Health, hereinafter referred to as NIH, a first settlement agreement was entered into on 30 March 1987, according to which Institut Pasteur and the DHHS agreed that "the existing technology" would be made available to the registered licensees at the date of signature of the agreement, as well as the improvement technology to the same licensees, provided that a licence has been granted by the patent holder. Annex C of the settlement agreement listed the applications and patents which were referred to, which included US patent applications No. 771 248 and No. 771 247 held by Institut Pasteur and filed on 30 August 1985.

US Patent No. 06/771 247 granted under the priority of French patent application No. 84 16013 in particular, describes the gp 110 protein.

On 22 February 1988, Institut Pasteur intended to file US patent application No. 07/158 652, a division of US patent No. 771 248, claiming UK priority No. 8 429 099 and French priority No. 84 16013 with Dr Alizon as the first designated inventor.

However, as Centocor, a company governed by the laws of the United States, had already filed, on 23 January 1985, US patent application No. 06/693 866, designating Dr Chang as the inventor and having, in part, the same subject-matter as Institut Pasteur's patent application No. 07/158 652, the USPTO started a procedure called "interference procedure" which aimed at determining which company, Institut Pasteur or Centocor, could claim the title.

On 1st December 1994, Institut Pasteur, Centocor, the DHHS/HIH and Dupont de Nemours, a licensee of Centocor, entered into a settlement agreement intended to put an end to the interference procedure; this agreement defines the details concerning the grant of cross-licences for implementing the technology presented in Institut Pasteur's US patent application No. 07/158 652 and in Centocor's US patent application No. 06/693 866.

As Institut Pasteur had noted that Abbott was marketing detecting kits that implemented, according to the former, three of its patents (EP 201 540 B2, EP 211 022 B1, EP 0 387 914 B1) which were not referred to in the 1994 settlement agreement, it served a summons for infringement upon Abbott France before the *Tribunal de Grande Instance* of Paris.

By way of a judgment dated 21 January 2009, the *Tribunal de Grande Instance* dismissed Abbott's plea of inadmissibility and its request to stay the proceedings, held that pursuant to the additional contract of 13 May 1996 and the reiterative agreement of 9 September 2005 entered into between the DHHS / NIH and Institut Pasteur, Abbott was authorised to exploit the patents at issue and dismissed Institut Pasteur's claims for patent infringement and Abbott's claim for damages for abuse of procedure.

Having regard to the last pleading filed on 8 April 2010 by Institut Pasteur, which contends in substance that US patent application No. 07/158 652 (division of US application No. 06/771 248, the subject-matter of the 1994 settlement agreement), is distinct from US application No. 06/771 247 so that the DHHS / NIH could not, on 13 May 1996, grant licence rights to Abbott over this US application No. 06/771 247; indeed, in the 1994 settlement agreement, clause 1.8 defines the "licensed products" as being common to the two interfering applications (07/158 652 and 06/693 866) which neither disclose nor claim the gp 110 protein claimed by US application No. 06/771 247 and by the foreign equivalents thereof which include the European patents claimed to be infringing in this case; Institut Pasteur adds that this same clause cites, as an example of products which are not licensed, applications GB 8 423 659 and FR 84 16013, both referred to as priorities by US patent application No. 06/771 247; yet, FR 84 16013 essentially relates to the gp 110 protein.

Institut Pasteur requests that the court record that it renounces its claims for infringement of claims 1, 4 and 8 of the French designation of European patent No. 0 211 022, find that Abbott holds no licence right over European patents No. 201 540 and No. 387 914, and that Abbott's Ax SYM, Ax SYM COMBO, DETERMINE, PRISM and IMX kits use a process and a kit for detecting the HIV-1 virus which implement the antigen of the envelope glycoprotein of the said virus (gp 110) and of fragments of this glycoprotein, which do not exceed 200 amino acids; it requests that the appealed decision be reversed, that the respondent be held liable for infringement of claims 1 and 17 of patent EP 0 387 914 and 16 of patent EP 0 201 540, that it pay to it the sum of 7,167,840 euros (calculated on the basis of a percentage of the turnover) as an advance payment to be deducted from the damages, the amount of which will be set after expert investigations, 500,000 euros as additional damages for having deliberately misapplied the provisions of the 1st December 1994 settlement agreement;

Having regard to the last pleading dated 27 May 2010 filed by Abbott France, which requests that the court affirm the appealed judgment in all its orders, puts forwards, in substance, arguments of inadmissibility, a plea drawn from the sublicence it was granted by the DHHD / NIH in accordance with the 1994 agreement, requests in fine that the patents asserted against it be held invalid, including patent EP 0 211 022, and in the very alternative, that the court hold the absence of evidence proving the infringement;

WHEREUPON,

On the argument drawn from a lack of power of the President of Institut Pasteur:

Considering that the respondent sets out that, since the President of Institut Pasteur did not justify that he had been authorised by the board of directors to initiate the infringement proceedings, the statement of claim should be held invalid pursuant to Article 117 of the French Code of Civil Procedure without requiring to demonstrate any charge;

However, considering that this argument of invalidity is inadmissible since it was not raised prior to all argument of defence on the merits of the case;

On the plea of inadmissibility:

Considering that Abbott alleges that the NIH – which granted the sublicence to Abbott – and Institut Pasteur had reached an agreement with respect to the reason of this dispute, in the last months of the first instance proceedings, and that the NIH had paid the owed royalties pursuant to the 1994 licence agreement with a cheque of 399,963 dollars dated 26 April 2007 which was duly cashed; that Abbott adds that Institut Pasteur's letter dated 8 February 2007 and addressed to the NIH refers to the kits for detecting the HIV-1, to the Alizon patents and to the settlement agreement, so that the settlement nature of the payment which was made and cashed would render inadmissible the appellant's infringement claims against Abbott, a sublicensed company whose rights were granted by the NIH;

However, considering that Abbott, which did not ask the NIH to join the proceedings, does not demonstrate by the above mentioned letter and the e-mails which may have been sent before, that the reason for the payment of 399,963 dollars was the use of the gp 110 protein and not that of other proteins falling within the scope of the products licensed according to the 1994 agreement;

That moreover and above all, these proceedings are not mentioned in these exchanges between the NIH and Institut Pasteur, to which the respondent was not part;

That since the renunciation of a right cannot be assumed, Abbot obviously does not establish that Institut Pasteur's action against it is inadmissible;

On the requests:

Considering that, like in first instance, the respondent asserts, as a main request, the existence of cross-licences over the two allegedly infringed patents granted pursuant to the 1st December 1994 settlement agreement; that it asserts, secondly, that both patents are not valid in order to request that they be held invalid;

That therefore, it should be determined, as did the first instance judges, whether the scope of the settlement agreement covers the gp 110 protein and, in the negative, and only in this circumstance, the validity of the asserted titles should be assessed;

On the scope of the 1994 settlement agreement:

On the applicable law:

Considering that this agreement, pursuant to Article 12.3 thereof, is governed by the Maryland State Law "*for the issues falling within the State Law and by the United States Law for issues falling under federal law"*.

Considering that, as stated in the according affidavits submitted by each party, it is established that in order to assess the scope and the meaning of an agreement, the State of Maryland invites the jurisdiction to "*determine from the language of the agreement itself what a reasonable person in the parties' position would have wanted to say at the moment this agreement is entered into…; when a word in the contract is ambiguous,*

a court should consider the circumstances and conditions affecting the parties at this moment and their later behaviour and interpretation of the contract…; when two provisions of a contract are apparently conflicting, they should, if possible, be interpreted so as to give effect to the parties' intention as it is clear from the whole document, the subject-matter of the agreement, the circumstances under which it was signed and its aim and purpose; and to determine the true meaning of a contract, the contract should be interpreted in whole (and each clause should be given a meaning) 'the court's interpretation should not achieve an absurd or unreasonable result'" (Mr Van Alstine's affidavit);

That the jurisdiction should also "*determine the common intention of the parties to the contract and give effect to it; by attempting to do so, the Maryland Law is based on an "objective theory of interpretation" (in accordance with this rule), a court will attempt first to determine the parties' intention from the wording of the written contract itself; taking mainly into account the usual meaning of the words used."* (Statements under oath made by Messrs Booth and Sandercrook);

Considering that pursuant to these principles of interpretation, the 1994 agreement should be put back in context, the purpose which was pursued by the parties should be specified and the terms in dispute should be interpreted within a meaning corresponding to their common intention in order to give full effect to their respective undertakings;

On the context:

Considering that it will be recalled that following the dispute concerning the determination of the first research team to discover and develop, in particular, the dosage of the antibodies developed against the HIV-1 virus, the American health authority, the DHHS / NIH and Institut Pasteur, noticing that the disputes opposing them went against their common interest, reached an agreement on 30 March 1987 according to which they decided to:

- put an end to the existing proceedings,

- establish a sharing procedure with respect to the income generated by the exploitation of the two patent applications respectively filed by Institut Pasteur in the United States (No. 558 109 No. 785 638) and by Professor Gallo (No. 4 520 113),

- set up a foundation intended to finance research for the emerging countries and the people suffering from AIDS,

- allow the licensees of each party to have access in principle to the "existing technology" at the date of signature of the agreement,

- allow the same licensees to have access to the "improvement technology", "on conditions that are not less favourable than those it offers to its own licensees";

Considering that annex C of this agreement lists the patents or patent applications held by each party which are concerned by this "improvement technology";

That this list expressly shows US patents No. 771 248 and No. 771 247 at issue in this case, which, the latter patent in particular, relate to the gp 110 envelope protein;

On the 1994 agreement:

Considering that the 1994 agreement follows on from that of 1987;

That, as recalled in the established facts, at the time it was signed, taking into account that Institut Pasteur had filed on 22 February 1988 in the United States patent application No. 07/158 652 (division of application US 06/771 248) while Centocor had filed on 23 January 1985 patent application No. 06/693 866 partly corresponding to Pasteur's application No. 07/158652, the USPTO had started a procedure of interference to determine which of the two applicants could claim the title;

That the subject-matter of the interference was described as follows: "*isolated env or env-lor DNA of HTLV-III with the sequence of figure 3 (of Centocor's patent application No. 06/693 866) or a sequence of nucleotides coding for an env or env-lor polypeptide with the sequence of amino acids as illustrated in figure 3…"*;

Considering that it is established that, as this procedure allowed them to do, the parties broadened the subject-matter of the interference to include thereto "*any remaining subject-matter which is common to the Alizon and Chang applications"* (US 07/158 652 and US 06/693 866) and in particular:

- an HIV-1 immunoreactive polypeptide expressed by the cells transformed with a recombining vector containing the HIV-1 DNA,

- diagnostic means containing either env or env-lor isolated DNA of HIV coding for an immunoreactive polypeptide, *i.e.* antibodies that are specific to these;

Considering that the purpose of the 1994 protocol was to put an end to this procedure of interference but, more importantly, to prevent all future discussion on what could appear as being common to the two patent applications at issue and to allow both the parties and their respective licensees to be granted-cross licences;

Considering that licensed subject-matter called "licensed product" is defined in clause 1.8, whose scope is disputed by the parties;

This article is translated as follows:

"'*Licensed product' means any product composed of, using or incorporating any of the following subject-matters common to Pasteur's US patent application No. 07/ 168 652 and Centocor's US patent application No. 06/ 693 8666*[1]*:*

(a) isolated DNA including the whole env, gag, pol or sor open reading frames of the HIV-1 genome or the fragments of these open reading frames,

(b) DNA probes including the whole env, gag, pol or sor open reading frames of the HIV-1 genome or fragments of these open reading frames,

[1] Translator's note: should read "866"

(c) polypeptides encoded by the whole env, gag, pol or sor open reading frames of the HIV-1 genome or fragments of these open reading frames, these polypeptides being produced by any recombining technique or chemical-synthesis technique,

(d) diagnostic kits incorporating the HIV-1 polypeptides or the HIV-1 DNA probes above produced by any recombining technique or chemical-synthesis technique,

(e) Monoclonal or polyclonal antibodies directed against a polypeptide encoded by the env, gag, pol or sor open reading frames or an DNA fragment thereof, this polypeptide being produced by any recombining technique or chemical-synthesis technique,

(f) HIV-1 vaccines including the polypeptides above produced by any recombining technique or chemical-synthesis technique, and

(g) therapeutic agents against HIV-1infection, including the DNA, polypeptides or antibodies above,

Provided that any product of this type is claimed in the Alizon Patent Rights or the Chang Patent Rights, filed or granted in the country where this product is manufactured, used or marketed. Any subject-matter, except for that listed in (a) through (g) above, which is not common to that disclosed in Pasteur's US patent application No. 07/158 652 and in DHHS/Centocor's US patent application No. 06/693 866 is beyond the scope of the Licensed Product for this settlement agreement, even if this subject-matter can be disclosed or claimed in one or several patents or patent applications identified in the Chang patent rights or the Alizon patent rights (for example, Pasteur's patent application GB 84/ 23659 or Pasteur's patent application FR 84 16013…etc)".

On the scope of the 1994 agreement:

Considering that in support of its request to reverse the appealed decision, the appellant sets out that US patent No. 06/771 247 was not licensed and is not referred to in this agreement insofar as "the licensed products" are only those that are common to the two interfering applications which neither claim nor disclose the gp 110 protein which is, however, claimed by US application No. 06/771 247 and by its foreign equivalent applications; that in addition, clause 1.8 mentions, as an example of a subject-matter which is beyond the licence scope, patent applications GB 84 23 659 and FR 84 16013, *i.e.* the two priorities of US patent application No. 06/771 247;

Considering that this has been recalled, it is true that US patent No. 06/771 247 relating to the gp 110 protein is not expressly mentioned in the 1994 agreement which, however, lists in its annex C the Alizon patent rights (EP 211 022, EP 201 540 and EP 387 914) on which the action for infringement is based;

Considering that in order to assess the scope of the contractual provisions in dispute, the Maryland State Law suggests that the jurisdiction take into account, as explained above, not only the usual meaning of all the terms used, but also the parties' common intention and the circumstances in which they were led to reach an agreement;

Considering in this respect that the 1987 agreement and the position adopted by the parties in 1992 within the framework of the procedure for interference before the USPTO enable to approach the contractual scope of the cross-licences;

Considering indeed that the 1987 agreement was entered into with the purpose of "*favouring the cooperation between Institut Pasteur and the NHS in their respective efforts for developing innovative techniques to diagnose AIDS, promote the research efforts of the other institutions on AIDS…*" and to restore "*the collective atmosphere of trust which is essential to freely exchange scientific information, which is so vital for efficient research work…"* ("Context" page 5 of the translation);

Considering that annex C of the agreement precisely mentions US patent No. 06/ 771 247 among the "improvement technologies" that the parties had undertaken to put at the disposal of the other party's licensees – section VI B.2;

Considering that it follows that US patent No. 06/771 247 is indeed one of those which the parties had agreed to licence within the framework of the improvement techniques;

Considering that the 1994 agreement not only does not substitute the 1987 agreement, but also claims the relation thereto with respect to the conditions in which the licences must be granted since clause 3.3 thereof states that "*each licence of the Alizon patent rights aiming at manufacturing, using or marketing the Licensed Product … will be considered as granted in accordance with the requirements of section VI B.2 of the 1987 agreement…"*, these provisions referring to the cross-licences that relate to the improvements of the existing technology;

Considering that the appellant argues that if the purpose of the 1994 agreement were to grant a licence for any product insofar as it is covered by a patent application or a patent listed in annex C, it would have been easy to draft this using simple terms, but that this is not what is provided for by clause 1.8 which gives a different definition of a "licensed product";

Considering indeed that clause 2.1 of the said agreement, drafted using general terms, certainly states that "*…Pasteur grants to the DHHS, Centocor … a licence…free of royalties on the Alizon patent rights"* (as listed in annex C), but adds that these licences are only granted in order to "*manufacture, have it manufactured for their own exclusive use, use and market the Licensed Product…"*;

Considering that, therefore, it is important to determine whether the definition of the "Licensed Product" given in clause 1.8 covers the gp 110 protein used in the diagnostic kits;

Considering that the gp 110 protein is the most important fragment of the "env" gene;

Considering that the products or subject-matters listed from (a) through (g) in clause 1.8 relate to the four main HIV genes, including "env" coding for the gp 110 envelope proteins and "gag" coding for the core proteins, the fragments or the probes of the HIV genome and of the four main genes, the polypeptides from the four main HIV genes as well as the fragments of these genes, the diagnostics kits using either the HIV polypeptides or DNA probes to reveal the presence or the exposure to the HIV;

Considering that according to the appellant, licences for the products listed in (a) through (g) are granted on the sole condition that they be common to the two patent applications subject-matter of the procedure for interference, so that points (a) through (g) would constitute the general framework according to which one should determine the subject-matters that could be licensed provided that they are common;

Considering that this interpretation is purely literal and only results from the sole presence of the adjective "common"; that it is never mentioned that in order to grant a licence for a product, one would have to demonstrate the common feature thereof with respect to the two interfering applications;

Considering that on the contrary, this same article, after having listed the products at issue in (a) through (g), provides that "*Any subject matter exclusive of that listed in (a) through (g) above, which is not common to that (of the interfering applications)… is beyond the scope of the 'Licensed Product'…"*; that the mention "subject matter exclusive of that listed in (a) through (g)" sufficiently means that the common feature is not a general condition which would be compulsory for each of the products or subject-matters listed in (a) through (g); that in other words, the exclusion does not concern the list (a) through (g);

That, furthermore, should the parties not have had such intention, they would have been careful to determine what could be considered as common with respect to each of these subject-matters since they intended to avoid the future difficulties arising from the said interference;

Considering finally that it is useful to point out that within the framework of the procedure of interference, the parties broadened the area of interference to add other subject-matters thereto, in particular an immunoreactive HIV-1 polypeptide expressed by the cells transformed by a recombining vector containing the HIV-1 DNA and more importantly all diagnostic means containing either the env or env-lor isolated DNA of the HIV coding for an immunoreactive polypeptide, *i.e.* antibodies that are specific to these;

That, therefore, they considered the abovementioned subject-matters and, consequently, the immunoreactive fragments of the designated genes (env), as "common" because they were referred to by the interference;

Considering that Institut Pasteur then asserts the fact that clause 1.8 shows, as an illustration of the exclusions from the licences scope, two French patent applications filed by Institut Pasteur, No. 84 23 659 and No. 84 16013, corresponding to the two priorities of US patent application No. 06/771 247, which would constitute, according to Institut Pasteur, the evidence that this latter application was indeed beyond the scope of the settlement agreement;

Considering, however, that the appellant, which was a party to the negotiations that led to the drafting of this clause, could have submitted to the court the projects and pre-contractual exhibits that would support its interpretation which leads to exclude the gp 110 by a simple mention in brackets, although this protein is expressly included in the list of the products (a) through (g) and mentioned by the parties to the settlement agreement in their request for interference;

Considering, however, that the appellant submitted no evidence in support of its singular interpretation of the example given *in fine* in clause 1.8;

Considering that, as pointed out by the respondent and as held by the first instance judges, the mention put between brackets to applications No. 84 16013 and No. 84 23 659, is only given as an example of the Alizon patents, whose scopes are broader than the sole gp 110;

Considering consequently that it sufficiently results from the context that governed the elaboration of the 1994 agreement, which must be read in reference to the 1987 agreement, from the purpose which the parties declared they wanted to pursue and from the definition of the "Licensed Product", that the gp 110 falls within the scope of the licensed products;

That the respondent is therefore founded in opposing to the action for infringement of European patents No. 201 540 and No. 387 914 a plea drawn from the sublicence it was granted by the DHHS/NIH;

On the request for abuse of procedure:

Considering that an action is considered as an abuse if it has been initiated in bad faith in the aim of harming the party upon which the summons was served or with an obvious negligence appearing from gross mistakes;

That the mere reckless nature of an action is not sufficient to make it abusive;

That in this case, the court points out that the respondent does not justify the damage it allegedly suffered from these proceedings, distinct from the irrecoverable costs incurred;

That, consequently, its request should be dismissed;

On Article 700 of the French Code of Civil Procedure:

Considering that justice demands that the appellant be ordered to pay to the respondent the sum of 40,000 euros for the irrecoverable costs incurred by the appeal proceedings.

ON THESE GROUNDS,

Holds that the plea of invalidity raised by Abbott France is inadmissible,

Holds Institut Pasteur's action admissible,

Records that Institut Pasteur renounces its claims based on the infringement of claims 1, 4 and 8 of the French designation of European patent No. 0 211 022,

Affirms the appealed decision,

Dismisses the claim for damages for abuse of procedure,

Orders Institut Pasteur to pay to Abbott France the sum of 40,000 euros pursuant to Article 700 of the French Code of Civil Procedure and to bear the costs of the appeal proceedings which will be recovered pursuant to Article 699 of the same Code.

The Clerk, The Presiding Judge,