FRENCH REPUBLIC
IN THE NAME OF THE FRENCH PEOPLE

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

Section 1 - Chamber 2

DECISION OF 21 MARCH 2012

(No. , pages)

Docket number: **11/12942**

Decision referred to the *Cour d'Appel*: Order of 21 June 2011 - *Tribunal de Grande Instance* of PARIS – Docket No. 11/52963

APPELLANTS

NOVARTIS AG, a company governed by the laws of Switzerland, represented by its legal representative

Lichtstrasse 35

4056

57340 BASEL (SWITZERLAND)

SAS NOVARTIS PHARMA represented by its legal representative

2/4 rue Lionel Terray

92500 RUEIL-MALMAISON

represented by SCP FISSELIER ET ASSOCIES (Mr Alain Fisselier) (attorneys-at-law, members of the Paris Bar, court box: L0044)

assisted by SCP DUCLOS THORNE MOLLET-VIEVILLE (Mr Thomas Cuche and Mr Thierry Mollet-Vieville) (attorneys-at-law, members of the Paris Bar, court box: P0075)

RESPONDENTS

MYLAN

117 allée des Parcs

69800 ST PRIEST

SAS QUALIMED

117 allée des Parcs

69008 ST PRIEST

represented by Mr Dominique OLIVIER (attorney-at-law, member of the PARIS Bar,
court box: D1341)

assisted by Mr Jean-Christophe GALLOUX (attorney-at-law, member of the PARIS Bar,
court box: E 146)

COMPOSITION OF THE *COUR D'APPEL*:

The case was discussed on 14 February 2012, in public hearing, before the *Cour d'Appel* composed of:

Ms Brigitte GUYOT, Presiding Judge

Ms Maryse LESAULT, Judge

Ms Michèle GRAFF-DAUDRET, Judge

who deliberated

Court Clerk, during the discussion: Ms Nadine CHAGROT

DECISION:

- AFTER HEARING ALL THE PARTIES

- made available at the Court Clerk's office, the parties having been previously notified under the conditions laid down in the second subparagraph of Article 450 of the French Code of Civil Procedure.

- signed by Ms Michèle GRAFF-DAUDRET, Judge, due to the unavailability of the Presiding Judge, and by Ms Nadine CHAGROT, Court Clerk.

ESTABLISHED FACTS:

Novartis AG is the holder of French patent FR 88 02 597 (hereinafter referred to as FR 597) filed on 29 February 1988 and published under number 2 611 707, claiming priority from German patent DE 3 706 914 4 dated 4 March 1987.

It relates to a molecule named "Rivastigmine", which is a phenyl carbamate with anticholinesterase activity useful in the treatment of senile dementia. Rivastigmine is marketed by SAS Novartis Pharma in France, under the name Exelon, for the symptomatic treatment of Alzheimer's disease and Parkinson's-related dementia.

Patent FR 597 was granted on 20 April 1990 to Sandoz. Novartis, a company governed by the laws of Switzerland, became the holder of the patent following the merger between Ciba-Geigy and Sandoz. The transfer of ownership was registered in the French patent register on 31 July 1997 under No. 103 845.

On 2 October 1998, Novartis AG applied for a supplementary protection certificate (SPC) based upon marketing authorisation EU/1/98/066/001 in particular, which covered Rivastigmine.

The application was registered in the French patent register on 20 October 1998 under No. 109 908.

The SPC was granted on 20 February 2001 under No. 98C 0033 and its grant was published in BOPI[TN] No. 01/09 of 2 March 2001.

[TN] The official industrial property bulletin

A licence for patent FR 597 and SPC 98 C 0033 (hereinafter referred to as 98C0033) was granted to the French company Novartis Pharma SAS and was registered in the French patent register on 11 February 2010 under No. 175 964.

The rights on this SPC expire on 31 July 2012.

Abroad, Rivastigmine, in the form of its hydrogen tartrate salt in particular, was patented in at least 15 countries, including the United States (patents US 5,602,176), Japan (patent 2 625 478) and Germany (DE 38 44 992).

Novartis became aware that Mylan and Qualimed were about to market drugs in France which, according to it, infringed SPC No. 98C0033.

On 1 and 4 October 2010, the *Agence Française de Sécurité Sanitaire des Produits de Santé* (AFSSAPS)[TN] granted Mylan and Qualimed the marketing authorisation (MA) for the proprietary drugs named Rivastigmine Qualimed and Rivastigmine Mylan (1.5, 3, 4.5, 6 mg, capsule). These MAs were filed under numbers DE/H/1665/001 to 004 and DE/H/1667/001 to 004 by Mylan, which transferred MAs numbers DE/H/1667/001 to 004 to Qualimed .

Pursuant to Article L. 5121-10 of the French Public Health Code, Novartis was informed of the grant by the AFSSAPS of these MAs for drugs that are generic drugs of the proprietary drug Exelon (1.5, 3, 4.5, 6 mg, capsule).

On 17 December 2010, Novartis Pharma reminded Mylan and Qualimed of their rights as well as those of Novartis AG on SPC No. 98C0033 until 31 July 2012, and requested that the defendants confirm that they would not commit direct or indirect acts of infringement of these rights. Mylan and Qualimed did not respond.

By way of a decision by the AFSSAPS dated 23 December 2010, the MAs for Rivastigmine Qualimed and Rivastigmine Mylan were registered in the index of generic drugs.

Novartis Pharma became aware that Mylan and Qualimed had filed an application with the *Comité Économique des Produits de Santé* (CEPS)[TN] for the registration of their proprietary drugs "Rivastigmine Qualimed" and "Rivastigmine Mylan".

On 17 February 2011, the CEPS informed Novartis Pharma that Mylan, which is the owner of Qualimed, had indicated that it "could market its generic drugs without infringing Novartis' rights over SPC No. 98C0033" and that it could market the drugs within six months following their registration in the Official Journal.

The drugs Rivastigmine Qualimed and Rivastigmine Mylan were registered in the list of refundable medicinal products on 29 April 2011.

The directions for use of the generic drug Rivastigmine Qualimed show that this drug is manufactured by SAS Mylan, in its registered office in Saint Priest or in its secondary establishment in Meyzieu, and that it is exploited by this same company.

The directions for use of the generic drug Rivastigmine Qualimed show that it is also manufactured by SAS Mylan and that it is exploited by Laboratoires Qualimed, whose company name is Qualimed.

By way of an act dated 17 March 2011, Novartis AG and Novartis Pharma summoned Mylan and

[TN] The French agency for the safety of health products, which grants, suspends or withdraws marketing authorisations for medicines

[TN] The French economic committee for health products

Qualimed to appear before the Judge ruling in preliminary proceedings in order, in particular, to enjoin them until 31 July 2012 from importing and/or manufacturing, holding, using, offering for sale and selling, and more generally from marketing the drugs Rivastigmine Mylan and Rivastigmine Qualimed (1.5 mg, 3 mg, 4.5 mg and 6 mg, capsules), under this name or any other name, infringing in particular the features of claims 1, 2, 4 to 6 and 8 of patent FR 88 02 597 and SPC No. 98C0033 , to forbid until 31 July 2012 all use of Rivastigmine, in particular for manufacturing, importing, holding, offering for sale and/or selling in France the drugs Rivastigmine Mylan and Rivastigmine Qualimed (1.5 mg, 3 mg, 4.5 mg and 6 mg, capsules), under this name or any other name, infringing in particular the features of claims 1, 2, 4 to 6 and 8 of patent FR 88 02 597 and SPC No. 98C0033, under penalty, to see that Mylan and Qualimed be consequently ordered to hand over to the bailiff the batches of capsules they hold as well as the corresponding technical and commercial documents and, finally, to obtain an order of publication of the judgment to be handed down.

By way of an order handed down on 21 June 2011 after hearing all the parties, the Judge ruling in preliminary proceedings of the *Tribunal de Grande Instance* of Paris, mainly on the grounds of the dispute relating to the lack of inventive step, based on the Proterra patent prior art document with the article published in 1986 by its inventor, Weinstock, and on a "FDA guideline of February 1987":

- dismissed all of Novartis AG and Novartis Pharma's claims against Mylan and Qualimed,

- dismissed Mylan and Qualimed's requests for damages for abuse of process,

- ordered Novartis AG and Novartis Pharma, jointly, to pay the sum of 30,000 euros to Mylan and Qualimed pursuant to Article 700 of the French Code of Civil Procedure,

- ordered Novartis AG and Novartis Pharma, jointly, to pay the costs.

Novartis AG and Novartis Pharma lodged an appeal against this decision on 8 July 2011.

The closing order was handed down on 8 February 2012.

NOVARTIS' CLAIMS AND ARGUMENTS:

In their latest pleading dated 7 February 2012, to which one should refer, Novartis AG and Novartis Pharma set out the following:

- *the current applicable text is Article L. 615-3 of the French Intellectual Property Code* which provides that the Judge ruling in preliminary proceedings may immediately enjoin the infringement when such infringement is "likely"; there is no condition provided for in the law; the immediate injunction is subject to the likelihood of the infringement only and not to that of the validity of the patent; the appealed order contains a "serious error" on this issue; if the patent seems obviously invalid to him, the "judge ruling on appearances"[TN] is certainly right in deeming the infringement not likely, however, the obviousness of the patent invalidity is not the criteria or the condition held in the order, as the first instance Judge thought he could hold that Novartis' patent was probably invalid although it is more than likely that this patent is valid, it being recalled that even

[TN] The Judge ruling in preliminary proceedings is sometimes referred to as the "*juge de l'apparence*" (judge ruling on appearances) or "*juge de l'évidence*" (judge ruling on obviousness) as he does not rule on the merits of the case but only renders an interim decision based on the elements that are brought before him.

a French patent is assumed to be valid, as are all the intellectual property titles registered by the competent authority,

- *on the likelihood of the infringement*,

the infringement of Novartis' patent and SPC by Mylan is neither disputed nor disputable; it is a generic drug, *i.e.* it copies the patented drug; there was no doubt nor any real dispute as to the imminence of the infringement before the first instance Judge.

- *on the validity of the patent*,

. they describe the invention (its subject-matter is a new phenyl carbamate in the form of its optical isomer S of formula I), and mention the covered claims (1, 2, 4, 5, 6, 8),

. since 1999, the new carbamate, called "Rivastigmine", has been exploited under the name EXELON,

. **the Proterra prior art document**,

. this patent discloses compounds of the phenyl carbamate type with an anticholinesterase activity, based on the principle that certain pathological and degenerative diseases, Alzheimer's disease in particular, are associated, among other things, with a reduction or selective loss of the cholinergic transmission, more particularly, in the case of Alzheimer's disease, with a selective loss of the enzyme that synthesises acetylcholine (ACh), which is a neurotransmitter; Ach is degraded by specific enzymes called "acetylcholinesterases"; ACh has an extremely short life; the aim of the anticholinesterasic molecules is to inhibit said acetylcholinesterases in order to compensate for the loss of activity of choline-acetyltransferase which synthesises acetylcholine; the Proterra prior art document discloses that the phenyl carbamate family (or phenyl carbamates) are 500,000 in number,

however,

. Proterra neither mentions nor suggests to the skilled person the possibility of a link between this known inhibition and its compounds of chiral form or non-chiral,

. Proterra in no way discloses the pharmacologically acceptable salt that will be claimed in claim 2 of patent FR 597: the hydrogen tartrate form,

. the *Cour d'Appel* should note that Proterra only provided examples for the hydrochlorides of its phenyl carbamates,

. Mylan's argument that the disclosure of a family of compounds also discloses all the members of this family and therefore that the disclosure of the tartrates by Proterra implies the disclosure of all forms of tartrates, including the hydrogen tartrate, is an interpretation of the notion of disclosure which is contrary to Article L. 611-11 of the French Intellectual Property Code,

. far from directing the skilled person towards a few examples illustrating the invention, Proterra prompts the skilled person to examine all the compounds likely to be part of this phenyl carbamate family discovered by Weinstock,

. although the phenyl carbamate referred to as RA7 (corresponding to the racemic mixture of the

compound according to this invention) is described as such, and although the skilled person knows it is a racemate, there is nothing in the Proterra prior art document that could lead the skilled person to one of the two isomers of this phenyl carbamate, in particular isomer S of claim 1 of patent FR 597, which will be named Rivastigmine, let alone to use the hydrogen tartrate salt instead of the hydrochloride salt; therefore, this Rivastigmine was still unknown at the date of publication of the Proterra prior art document, on 10 September 1986,

. the in vitro and in vivo anticholinesterase activity was tested and measured by Proterra, as was toxicity, but it does not result from these analyses that, as asserted by Mylan, the "RA7 compound clearly emerges as the best candidate", which Mylan acknowledged in its pleading No. 2 of 31 January 2012 (p. 26),

. to conclude, the inventors of the Proterra patent considered that the preferred compounds among those given as examples were RA4, RA5, RA6, RA15, RA14, RA7 and RA8, and not RA7 alone, because these compounds all have a longer duration of action and a good therapeutic index,

. it should be kept in mind that although the Proterra prior art document discloses more than 500,000 phenyl carbamate salts, it constitutes only one possibility among the 288 possibilities available to the skilled person in 1987 to treat Alzheimer's disease,

. Novartis was granted a licence of the Proterra patent and of corresponding SPC No. 98C38, which expired on 4 March 2011; patent FR 597, which relates to the inventive selection of a compound in the phenyl carbamate family disclosed by Proterra, depends on this patent,

. the Weinstock publication,

the Judge ruling in preliminary proceedings, who held that the lethal effect of RA7 can be "prevented by atropine", could not interpret the Proterra and Weinstock prior art documents to consider only certain particular advantages of one of their compounds, such as RA7, without taking their disadvantages into account, while everyone knows that one disadvantage alone is sufficient to exclude the advantages of a compound; in addition, this beneficial effect also concerned six other tested compounds; Mylan contradicts itself in its pleading No. 3 as it sometimes indicates that the reduction of the toxicity through the atropine pre-treatment "is not decisive" and sometimes that it is "of utmost importance"; Mylan did not deem it useful to mention this article in support of its summons for invalidity of patent FR 597 which it alleges had been prepared for a long time,

- on the asserted state of the art, Mylan submits, for the first time on appeal, 25 new documents; the appellants discuss several articles (Easson, Casy, Jean-Jacques, Palmer Taylor) and the drugs mentioned by Mylan; the documents published after the filing date of the patent application, *i.e.* 4 March 1987, are not part of the state of the art pursuant to Article L. 611-11 of the French Intellectual Property Code, namely in particular the guidance given by the American administration (FDA) dated April 1987, construed in this case by the first instance Judge in a way which is opposed to that held by the *Tribunal* of Paris in its judgment dated 30 September 2010, concerning a case on the merits relating to a similar patent; this document was made available to the public as from 3 April 1987 only (contrary to the date mentioned thereupon: "February 1987"); in any case, this document only constitutes guidance given to the pharmaceutical companies for providing adequate documentation in support of their medicinal product application for the manufacturing of drug substances; contrary to what "Mylan may have led the first instance Judge to believe", this document does not mention that the isomers of the chiral molecules must be separated; nothing in this guideline prompts the skilled

person to choose chiral molecules (or racemates); the case law of the *Tribunal* of Paris is consistent with the decisions of several patent offices in the world,

- the subsequent documents or the documents whose availability to the public at the patent priority date is not demonstrated are not part of the prior art, nor are the Spot letter dated 8 May 1989, the Shindo article published in 1991, the Thal article published in 1988, the Kumkumian presentation, the Drayer and Carter presentations, the works of the inventor Enz, the exhibits which have not been translated into French,

- on the inadmissibility of Mylan's requests, Mylan's request for invalidity of claims 3 and 9 to 13 which are not asserted against it in these proceedings is inadmissible,

- **on the novelty of patent FR 597,**

. the compound of claim 1 does constitute a molecule which had been unknown until 4 March 1987,

. the same is true of this compound in the form of a hydrogen tartrate salt covered by claim 2,

. Mylan could not convince the first instance Judge that the racemic mixture can be confused with each of these isomers; neither the Proterra nor the Weinstock prior art document had described this isomer, namely Rivastigmine, even if these documents mentioned such a RA7 racemic mixture among almost 500,000 phenyl carbamate salts mentioned before 1987,

. the selection of the Rivastigmine isomer *is* new, according to the EPO's own case law,

- **on the non-obviousness of patent 597**,

. the condition for inventive step is determined by an in-depth examination and assessment,

. all reasoning made with hindsight should be avoided; it appears that the compounds in the patent at issue have an improved anticholinesterase activity in comparison to those of Proterra; consequently, the technical problem at hand was to provide compounds having an improved anticholinesterase activity and not to seek to separate the enantiomers of the compounds of Proterra because, in reality, such a statement already contains the solution to the problem, this is the reason why the research team representing the skilled person must not include a chemist specialising in the separation of enantiomers as this would amount to foreseeing the solution and therefore reasoning with hindsight; moreover, the skilled person was not used to systematically separating the enantiomers of a racemic mixture at the priority date of 1987; at that date, he was attempting to identify a compound having an improved inhibiting activity without being toxic and was not interested in whether or not this compound was of a chiral nature nor was he concerned with the possible separation of its enantiomers,

. the invention of the Rivastigmine presents an inventive step which has been recognized by the American and German patent offices in particular (and by 14 patent offices in the world overall) which, after carrying out complete examinations, accepted to grant the patent in issue in 1997 and 2006 (in spite of opposite Swedish decisions); it does not seem likely that the Judge ruling in preliminary proceedings, ruling on appearances, could render an opposite decision within a few days, as the appellants criticised, in a detailed manner, the grounds set out in the appealed order, while further specifying that on 30 September 2011, the Hon Mr Justice Floyd decided to hold Novartis' UK patent and the corresponding SPC invalid, but that this decision was subject to a request for an authorisation to lodge an appeal, in accordance with UK law.

They request that the *Cour d'Appel*:

- hold that their appeal is admissible and that their requests are well-founded,

- reverse the appealed order in all its provisions,

- hold that Mylan and Qualimed's requests are inadmissible and ill-founded,

- set aside from the discussion exhibits LA37, 40 to 46, 52, 53 and 55 to 64 which are not translated into French,

1/ a) - hold that even a serious dispute on the validity of the patent does not constitute sufficient grounds to reject the immediate interim injunction provided for in Article L. 615-3 of the French Intellectual Property Code,

- hold that in French and international law – in Article L. 615-3 of the French Intellectual Property Code in particular – the only requirement for an immediate interim injunction order is that "evidence, reasonably accessible to the claimant, make it likely that its rights are infringed or that such infringement is about to be committed",

b) - hold that the dispute put forward by Mylan and held by the Presiding Judge concerning the lack of inventive step of the patent is not likely, insofar as it is contrary to:

- the decisions of several patent offices around the world (in the U.S.A, in Germany and in Japan, in particular) which, in view of the same arguments and documents as those asserted by Mylan, recognized the inventive step of the patent at issue,

- the case law of the *Tribunal de Grande Instance* of Paris on the definition of the problem to solve and that of the skilled person, as well as on the inventive step involved in patenting an enantiomer,

- hold that in this case, the infringement is not only likely, but it is also certain insofar as it is obvious and not disputed by Mylan itself,

2/ - enjoin Mylan SAS and Qualimed SAS from manufacturing, offering, putting on the market, using, importing and/or holding these generic drugs which, under the denomination "Rivastigmine Mylan" and "Rivastigmine Qualimed" in particular (1.5 mg, 3 mg, 4.5 mg and 6 mg in the form of capsules in particular) use the means of claims 1, 2, 4, 6 and 8 of patent 88 02 597 and SPC 98C0033 until the expiry of the SPC on 31 July 2012,

- order, at Mylan SAS and Qualimed SAS's expense, the recall and the confiscation of the generic drugs "Rivastigmine Mylan" and "Rivastigmine Qualimed" from the distribution networks until the expiry of the SPC on 31 July 2012,

- hold that these injunctions, recalls and confiscations will be pronounced under a penalty of 1,000 euros per recorded infringement or per infringing milligramme whether in loose form or in packaged form, under a penalty of 50,000 euros per late day,

- hold that the *Cour d'Appel* will reserve the right to set the penalties,

3/ - note that they present, in France in particular, all the security (whether it consists in immovable or movable property or bank security) for the possible payment of compensation to Mylan SAS and/or Qualimed SAS in case the injunction later turned out to be not justified,

4/ - order Mylan SAS and Qualimed SAS, "jointly and severally", to pay the sum of 200,000 euros to each to each of them in compensation for the costs of the proceedings pursuant to Article 700 of the French Code of Civil Procedure,

- order MYLAN SAS and QUALIMED SAS, jointly and severally, to pay the entire costs of the proceedings, and to grant them the benefits provided for in Article 699 of the French Code of Civil Procedure.

MYLAN AND QUALIMED'S CLAIMS AND ARGUMENTS:

In their latest pleadings dated 8 February 2012, to which one should refer, Mylan and Qualimed set out the following:

- they consider that SPC No. 98C0033 is invalid because there are grounds which could have justified that the basic patent, patent FR 2 611 707, be held invalid,

- they develop arguments according to which this basic patent (which comprises 13 claims including three independent claims) is invalid,

- the state of the art closest in date to patent FR 2 811 707 priority claim, *i.e.* 4 March 1987, was made up, firstly, of documents relating to the RA7 selection (European patent EP 193 926 published on 10 September 1986, (the Proterra patent), the article by Weinstock (1986), the article by Palmer Taylor (1985)), and secondly, of documents relating to the separation of the isomers (listed p. 21),

- the skilled person may be defined, as he was by the first instance Judge, as being part of a team comprising an organist chemist or a pharmacist specialising in organic molecules with a therapeutic purpose and their synthesis, a pharmacist specialising in the study of organic molecules and an analytical chemist specialising in the analysis of the separation of organic molecules with a therapeutic purpose, on the grounds that long before the filing date of the patent application, the molecule, racemic RA7, had already been chosen,

- at the filing date of the patent in issue, the candidate for the solution to the technical problem that was posed was compound RA7; the problems are solved by a small number of carbamates, some of which are racemic compounds, to which the tartrates belong (table p. 24); the Proterra patent application confirms that compound RA7 meets all the criteria mentioned in the patent preamble, namely a better technical index which is defined by lower toxicity, longer activity and an improved chemical stability,

- the Proterra document unambiguously directs the skilled person towards the selection of RA7, in an obvious manner,

- the Weinstock article does belong to the prior art because its publication date cannot be disputed; this publication relates to the study of certain "preferred compounds" of the Proterra patent and among the examined products, compounds RA6 and RA7 perform clearly better than physostigmine; the Hon Mr Justice Floyd, in his decision dated 30 September 2011, concludes that compound RA7 was an obvious choice of compound to develop; concerning the documents submitted pursuant to the communication order of the UK Judge, it should be noted that as of January 1986, the entire correspondence between Professor Weinstock and Sandoz related to only one compound, namely RA7; at the filing date of the patent in issue, the separation of the isomers of RA7 was obvious, as it was considered a routine operation, advised by the regulatory authorities,

- in the FDA guideline, it is clearly recommended by the American Federal Administration that the isomers and their properties be tested during the development of a new pharmaceutical product; all these guidelines had been published beforehand in the form of a draft,

- there were Japanese guidelines (Shindo article, Kumkumian article) as well as other

publications (Casy article, Jacques book, Leigh article, Easson article),

- the EPO (European Patent Office) practice and decision T 296/87 of the Board of Appeal dated 30 August 1987 in particular states that an isomer may be patentable if the skilled person has not been prompted to separate the said isomers or if the separation requires using techniques which were not available,

- they present, as an extra argument, the drugs known at the filing date of the patent in issue; these documents have no link with Alzheimer's disease but describe a general context useful for the understanding of the dispute,

- claim 1 and dependent claims 2, 4, 5, 6, 7 are deprived of inventive step,

. claim 1 is deprived of inventive step; Rivastigmine is not a new molecule; the racemic mixture corresponding to the two isomers of Rivastigmine is known under the code RA7 of the Proterra patent and of the Weinstock article as well as its pharmacological properties; moreover, Rivastigmine is part of a compound family of which one of the precursors is physostigmine, mentioned in the common general knowledge of the Proterra patent; the first instance Judge rightly held that the skilled person developed no inventive step in carrying out routine tests and effects on molecule RA7; the two conditions laid down by case law to acknowledge the patentability of a "selection invention" are not met, namely:

1/ the skilled person was strongly prompted to separate the isomers given the regulatory context, the knowledge of the different properties of the isomers of the products belonging to this family and the possible toxicity in particular,

2/ the separation of the said isomers presented no difficulties as the techniques had been known since 1935 and had been widely used and as the isomer had been obtained as of March 1986,

. the same is true concerning claim 2, the tartrate is mentioned in the salts described in the article by White and in the Proterra patent,

. the same is also true concerning claim 4, as the use of the product as a drug is known from the Proterra patent,

. concerning claims 5, 6 and 7, the pathologies to which the patent refers are all mentioned in the Proterra patent,

. (process) claim 3 is also deprived of inventive step; it has no new technical feature in relation to the prior art (Masako article, Jacques book),

. concerning claim 8 (pharmaceutical composition), the Proterra patent describes pharmaceutical compositions including the racemic mixture of Rivastigmine,

. claim 9 and dependant claims 10 to 13 are also deprived of novelty or inventive step.

They request that the *Cour d'Appel*:

- hold their pleading admissible, hold their requests well-founded and accede to them,

- affirm the appealed order,

- note that infringement is not likely as SPC 98C0033 is probably invalid,

- dismiss all of Novartis AG and Novartis Pharma SAS's claims and arguments,

- order them, jointly, to pay 60,000 euros to both Mylan and Qualimed pursuant to Article 700 of the French Code of Civil Procedure,

- order them, jointly, to pay the entire costs, which will be recovered by Mr Dominique OLIVIER, attorney-at-law.

WHEREUPON, THE *COUR D'APPEL*

On the inadmissibility of an exhibit submitted in preliminary proceedings:

Considering that pursuant to Article 445 of the French Code of Civil Procedure, after the closure of the discussion, the parties may file no written submission in support of their observations, except to reply to the arguments developed by the *Ministère Public*[TN], or upon the request of the Presiding Judge in the cases provided for in Articles 442 and 444;

That, as no submission has been requested from the parties, the decision of the London Court of Appeal, communicated by Mylan and Qualimed after the oral hearing, will be held inadmissible;

On the request for rejecting exhibits:

Considering that the ordinance of Villers-Cotterêts dated 25 August 1539 established French as the prior and exclusive language before the national jurisdictions; that exhibits LA 37, 40 to 46, 52, 53 and 55 to 64 submitted to the discussion by the respondents, which are not translated into French, should therefore be set aside from the discussion;

On the "merits":

Considering that pursuant to Article L. 615-3 of the French Intellectual Property Code, "any person with authority to bring an action for infringement may, in preliminary proceedings, request the competent civil court to order, under a penalty of a daily fine if necessary, against the alleged infringer or intermediaries whose services it uses, any measure aimed at preventing an infringement about to be committed against rights conferred by the title or aimed at stopping any further allegedly infringing act.

The court, in preliminary or *ex parte* proceedings, may order the requested measures only if evidence, reasonably accessible to the claimant, make it likely that its rights are infringed or that such infringement is about to be committed";

Considering that the procedure provided for by these provisions is autonomous and that the conditions for its application differ from those set by Articles 808 and 809 of the French Code of Civil Procedure;

That it is up to Novartis AG and Novartis Pharma SAS to demonstrate that the evidence and the titles in their possession make it likely that an infringement of their rights, through the manufacturing and selling of the generic drugs Rivastigmine Mylan and Rivastigmine Qualimed, is about to be committed;

That it is not disputed that these drugs, which constitute generic drugs, *i.e.* products that are drugs having the same qualitative and quantitative compositions in active ingredients as the reference drug

[TN] The *Ministère Public* is composed of public servants representing the State and public interest in the judicial process. It has an advisory role and is independent from the parties. The *Ministère Public* is under the control of the Minister of Justice.

as well as the same pharmaceutical form, copy the drug covered by SPC 98C0033, whose rights benefit Novartis and expire on 31 July 2012;

Considering that it is established that on 1 and 4 October 2010, Mylan obtained from the AFSSAPS the authorisation to put on the market the generic drugs under the above-mentioned denominations, this authorisation having been transferred by Mylan to Qualimed; that on 23 December 2010, the MA for Mylan's generic drugs was registered in the index of generic drugs; that on 29 April 2011, Mylan's generic drugs were registered in the list of refundable medicinal products;

Considering that the legislator authorised generic manufacturers to carry out all the necessary formalities to place on the market their products before the extinguishment of the intellectual property rights over the proprietary drug as provided for in Article L. 5121-10 of the French Public Health Code; that they might thereby also have their product registered in the list of refundable medicinal products and in the index of generic drugs; these formalities being completed subject to notification of the right holder;

Considering therefore that the mere fact that the steps taken in accordance with these legal provisions were taken by Mylan and Qualimed before the expiry of Novartis' rights is not sufficient to demonstrate the imminent infringement of the latter's rights; that the simple letter of warning sent by the right holders to Mylan on 17 December 2010 is no more conclusive;

That, however, on 17 February 2011, Novartis Pharma had been informed by the CEPS that "Mylan had confirmed that it could market its generic drugs Rivastigmine Mylan and Rivastigmine Qualimed without infringing the declared rights, within six months following the registration in the Official Journal", therefore before the expiry of Novartis' rights;

That, therefore, the infringement of the rights conferred by the title is imminent, subject to the discussion relating to the validity of this title, the subject-matter of the dispute;

Considering that a patent is assumed to be valid; that about fifteen patent offices in the world, including the European, American, German and Japanese offices, have granted the patent covering the invention belonging to the appellants;

Considering that Mylan and Qualimed assert a lack of inventiveness, which is likely to deprive of validity patent FR 597, whose claimed protection extends to SPC No. 98C0033;

Considering that, while it is true that the conditions for acceding to the requested injunctions provided for in Article L. 615-3 of the French Intellectual Property Code are not met, as the rights whose protection is claimed are not characterised and as the validity of the claims is challenged due to a lack of inventive step, the appraisal of the Judge ruling in preliminary proceedings should not lead him to decide based on the seriousness of the action on the merits, *i.e.* of the action for invalidity of the title itself, such appraisal being now forbidden by the 29 October 2007 act;

That this act merely subordinated the measures of Article L. 615-3 to the likelihood of the infringement of the protected rights and not to the likelihood of the validity of the patent from which they derive; that, before the Judge ruling in preliminary proceedings, ruling on obviousness, only the obvious invalidity of the title can make it unlikely that these rights are about to be infringed;

Considering that Mylan and Qualimed assert that patent EP 926 of 1985, referred to as Proterra, constitutes a prior art document highlighting preferred compounds particularly interesting in the treatment of Alzheimer's disease, and more particularly the RA7 molecule; that it was sufficient, according to them, to perform routine tests and assays to verify that it had a significant effect on the acetylcholinesterase of the brain and could thus efficiently treat this disease;

Considering that, unless he is setting himself up as a scientist, the Judge ruling in preliminary proceedings, in view of his powers, cannot consider it obvious that, among the preferred molecules of Proterra (RA4, RA5, RA6, RA15, RA14, RA7, RA8), the RA7 molecule had been particularly highlighted in comparison to the other molecules of which some had similar properties; that the separation of the isomers of this molecule had been recommended by Proterra, or at least by the FDA (Food and Drug Administration) guidelines, and that this separation was obvious, as it only required a few routine tests, while the respondents themselves underline the necessary interpretation of scientific documents and analyses, as they mention, concerning the Weinstock article (p. 28 of their pleading) which they present as a publication "relating to the study of certain *preferred compounds* of the Proterra patent": "Professor Rosset affirms that among the products studied in this publication, none of these products is better than the others. It seems that Pr. Rosset misinterpreted the results given in this publication";

That the fact that patent FR 597 was filed quickly after the pioneer patent, pointed out by the first instance Judge, does not demonstrate in an obvious manner that the performed works *were* routine tests;

Considering also that although they had been granted the MA for their generic drug on 1 and 4 October 2010, and had decided to market it approximately fifteen months before the expiry of the SPC in issue which they argue is probably invalid, and although patent FR 597 had been filed for approximately twenty years, Mylan and Qualimed served a summons upon Novartis in order to "note the invalidity of all the claims of patent FR 2 611 707 (FR 597) for lack of novelty or inventive step, and, therefore, hold SPC FR 98 C 0033 invalid", before the Judge ruling on the merits only on the day after the summons to appear in preliminary proceedings which had been served upon them by the holders of the protection;

That, however, Mylan and Qualimed only had to serve the summons for invalidity of the said patent within the time limit allowing them to obtain a judgment on the merits, before proceeding, if necessary, to the marketing of the drug at issue, in order to avoid infringing the rights of the holders of this patent;

Considering, therefore, that it is likely that the rights of these holders are about to be infringed;

That the appealed order will be reversed and that the *Cour d'Appel* will order the injunctions detailed in the ordering part, which aim at preventing and putting an end to the infringement, and which are proportionate to the respect of Novartis' intellectual property rights;

That there is no reason to make other observations, especially in view of the security provided by Novartis which, in this case, is not called into question;

Considering that it would be unfair to let Novartis bear the irrecoverable costs incurred in these proceedings;

Considering that Mylan and Qualimed, which have been unsuccessful, will be ordered to pay the costs of the first instance and appeal proceedings, which may be recovered pursuant to the provisions laid down in Article 699 of the French Code of Civil Procedure;

ON THESE GROUNDS:

Holds that the exhibit submitted by the respondents after the oral hearing is inadmissible,

Sets aside from the discussion exhibits LA 37, 40 to 46, 52, 53 and 55 to 64 submitted by the respondent,

Reverses the appealed order, except in that it dismissed Mylan and Qualimed's request for compensation for abuse of process,

Ruling again,

Enjoins SAS Mylan and SAS Qualimed from manufacturing, offering, putting on the market, using importing and/or holding the generic drugs which, under the denomination "Rivastigmine Mylan" and "Rivastigmine Qualimed" in particular (1.5 mg, 3 mg, 4.5 mg and 6 mg in particular, in the form of capsules), use the means of claims 1, 2, 4, 6 and 8 of patent 88-02597 and of SPC 98C0033, until the expiry of the said SPC on 31 July 2012,

Orders, at SAS Mylan and SAS Qualimed's expense, the recall and the confiscation of the generic drugs "Rivastigmine Mylan" and "Rivastigmine Qualimed" from the distribution networks, until the expiry of SPC 98C0033 on 31 July 2012,

Holds that these injunctions, recalls and confiscations are pronounced under a penalty of 1,000 euros per recorded infringement or per infringing milligramme, whether in loose form or in packaged form, under a penalty of 50,000 euros per late day within 8 days following the service of this decision,

Holds that the *Cour d'Appel* does not reserve the right to set the penalties,

Orders SAS Mylan and SAS Qualimed, jointly, to pay the costs of the first instance proceedings,

Adding thereto,

Orders SAS Mylan and SAS Qualimed, jointly, to pay the global sum of 30,000 euros to Novartis AG, a company governed by the laws of Switzerland, and to SAS Novartis Pharma pursuant to Article 700 of the French Code of Civil Procedure,

Orders SAS Mylan and SAS Qualimed, jointly, to pay the costs of the appeal proceedings, which may be recovered pursuant to the provisions of Article 699 of the French Code of Civil Procedure.

THE COURT CLERK ON BEHALF OF THE PRESIDING JUDGE

THE JUDGE