5 January 1993

PRESIDENT OF THE DISTRICT COURT OF THE HAGUE

Judgment in interim injunction proceedings
given in the case with case number 92/1181 of:

1. the company under French law Rhône Poulenc Rorer S.A.,
   established in Paris-Antony, France,
2. the private company with limited liability
   Rhône Poulenc Rorer B.V.,
   established in Amstelveen.

plaintiffs 1 and 2,
attorney of record: S. de Wit

and of:

3. the private company with limited liability
   Smith Kline & French B.V.,
   established in Rijswijk, Z.H.,

plaintiff 3,
attorney of record: C.J.J.C. van Nispen,

versus:

1. the private company with limited liability
   Pharmachemie B.V.,
   established in Haarlem,
2. the company under French law
   Prographarm Laboratoires S.A.,
   established in Chateauneuf-en-Thymerais, France,
3. the company under French law
   Prographarm International S.A.,
   established in Chateauneuf-en-Thymerais, France
4. the company under French law Francochim S.A.,
   established in Goyrans, France
5. the company under French law Biostabilex Urap S.A.,
   established in Paris, France,

defendants,
attorney of record: D. den Hertog.

1. The course of the proceedings

The plaintiffs summoned the defendants to appear at the President's session for the hearing of interim injunction proceedings of 14 December 1992, which session was subsequently, in consultation with the parties, appointed for 18 December 1992. On the latter date the parties had

their positions explained by their attorneys of record, while plaintiff 3 filed an additional claim. After the parties had filed their statements of reply and rejoinder, they requested judgment and submitted the documents in the case. These included the written summaries of the arguments in court.

In the following the parties will be referred to as Rhône Poulenc cum suis (each individually as Rhône Poulenc S.A., Rhône Poulenc B.V. and SKF, respectively), and Pharmachemie cum suis (each individually as Pharmachemie and Prographarm Labs or Prographarm Int., Prographarm Int., Francochim and Biostabilex, respectively).

2. The facts

In the present proceedings the following facts are assumed to be established facts:

- Rhône Poulenc S.A. is the proprietor of the French patent 2.153.875, for a "nouveau procédé de préparation de l'acide (benzoyl-3-phenyl)-2 propionique", which patent lapsed on December 3, 1991 and with respect to which patent a certificate of supplemental patent protection (Certificat Complémentaire de Protection, CPP) was granted on June 26, 1992 under number 91 c 0001, which will be valid until December 3, 1998;

- the claim of the aforesaid patent reads as follows:

  Procédé de préparation de l'acide (benzoyl-3 phényl)-2 propionique caractérisé en ce que l'on affectue une réaction de Friedel et Crafts entre le (chloroformyl-3 phényl)-2 propionitrile et le benzène puis hydrolyse le produit obtenu en acide (benzoyl-3 phényl)-2 propionique qui est éventuellement transformé en sel métallique ou en sel d'addition avec une base azotée.

- on 28 September 1992 Prographarm lodged an appeal against the grant of the CPP with the Court of Appeal of Paris;

- The pharmaceutical preparation of Rhône Poulenc that is produced by the patented process is known by the generic name Ketoprofen and is sold on the Netherlands market by Rhône Poulenc B.V. under the trademark Orudis and by SKF as a licensee under the trademark Oscorel;

- Francochim is selling Ketoprofen, produced in Italy by FIS/SIMS by the patented process, in bulk to Prographarm;

- In France, Prographarm Labs. works Ketoprofen into capsules of 50, 100 and 200 mgs. Biostabilex sells these capsules in France under the name Topfen;

- Since 28 July 1992 an action for patent infringement against Prographarm, Francochim and Biostabilex is pending in France in full proceedings for judgment on the merits;

- Pharmachemie is buying capsules from Prographarm Int. under the name Ketoprofen Retard PCH 200;

- In the register of the Medicines Assessment Board Prographarm Labs. is registered as manufacturer of Ketoprofen PCH Retard and Pharmachemie as importer;

- On 28 October 1992 SKF registered a pictorial mark for the Benelux under no. 787891, consisting of the colour combination red/transparent green on a capsule for "pharmaceutical preparations and substances, specifically a preparation against rheumatism" (class of goods 5);

- Pharmachemie cum suis also provide the capsule of their pharmaceutical preparation with the colour combination red/transparent green.

3. The claims, the foundation therefor and the defence

3.1 Essentially, including the additional claim of SKF, Rhône Poulenc c.s. make the following claims:

Primarily:

a. an injunction ordering Pharmachemie cum suis to discontinue and in the future refrain from all infringements of the French patent 2.163.875 and the CCP no. 91 C 0001, respectively, which are valid in France and have been granted for the French territory;

Alternatively:

b. an injunction forbidding Pharmachemie to commit tort by provoking patent infringement by (any of the other) defendants or by enabling same to infringe the patent in France or by inducing (any of) the other defendants to infringe the patent in France by exporting Ketoprofen

Retard PCH 200 - obtained unlawfully - to the Netherlands or by causing such exports to be effected;

More alternatively:

c. an injunction ordering Pharmachemie cum suis, each individually and/or jointly, to discontinue and in the future refrain from all exports, whether direct or indirect, to the Netherlands of any Ketoprofen product which infringes the (supplemental) patent of Rhône Poulenc S.A.

Primarily and (more) alternatively:

d. all the above subject to a penalty of NLG 1,000.-- for each capsule or NLG 5,000.-- for each 10 grams of Ketoprofen with which, and/or NLG 1,000,000.-- for each day that (any of the) defendants infringe any prohibitory and/or mandatory injunction,

e. an injunction forbidding Pharmachemie cum suis to infringe the trademark of SKP;

f. an injunction forbidding Pharmachemie cum suis the use of the colour combination red/transparent green for any pharmaceutical preparation and/or substance;

g. an injunction ordering Pharmachemie cum suis to fetch back, within 48 hours after service of this judgment, all ketoprofen capsules in the colour combination red/transparent green supplied by them to customers in the Benelux, or to recall same while offering reimbursement of expenses, and subsequently either to destroy both the recovered capsules and the capsules still in stock or to export them to a non-Benelux country;

h. all the above subject to a penalty of NLG 5000.-- for each capsule and/or NLG 100,000.-- for each day that (any of the) defendants violate any of the prohibitory or mandatory injunctions mentioned under e to g inclusive;

i. with award of costs.

3.2 Rhône Poulenc cum suis have founded the claims under a to d inclusive on the rights of Rhône Poulenc S.A. under the French patent no. 2 163 875 and the CPP based thereon which are infringed, so they allege, by defendants 2 to 5, and on

the allegation that Pharmachemie is committing tort by provoking such infringement or by unlawfully profiting from it.

They have founded the claims under e to h inclusive on the rights arising under the aforementioned Benelux registration of SKF.

3.3 Pharmachemie cum suis have defended the action, stating reasons therefor.

4. Judgment of claims a to d inclusive

4.1 First of all, Pharmachemie cum suis queried whether the President is authorized to take cognizance of the claims.

Unquestionably, given the place of establishment of Pharmachemie, the President of the District Court of Haarlem has jurisdiction under art. 6, first sentence and par. 1, of the Convention on Jurisdiction and the Enforcement of Judgments in Civil and Commercial Matters (EEX). Since Pharmachemie cum suis declared at the court hearing that they wished to dispute only the jurisdiction of the Dutch courts and did not wish to invoke the relative incompetence of the Hague President, the latter may hold himself competent pursuant to the said article. The same applies with respect to his competence to issue interim injunctions under art. 24 EEX.

4.2 This competence is not barred by art. 16 paragraph 4 EEX. There is no question of an action which pursuant to this paragraph falls under the exclusive jurisdiction of a court of another Contracting State.

To the extent that the issue of the validity of the patent (or in the present case the "Certificat Complémentaire de Protection" (CCP)) is put forward as a defence, proceedings in a procedure on the merits may be suspended or judgment may be deferred until the competent court will have decided the issue of validity. Article 16, par. 4, has no applicability whatsoever to interim injunction proceedings. This does not mean, however, that the fact that a different court has exclusive jurisdiction on the validity of the patent is entirely irrelevant.

4.3 The jurisdiction of the Dutch court is not barred either by section 54 of the "Loi du 27 juin 1984, modifiée par la loi du 26 novembre 1990", since this jurisdiction must be

decided according to Dutch (procedural) law, including the EEX convention. Again, this does not mean that the fact that an action for infringement is already pending in a procedure on the merits in the French court must be left entirely out of consideration.

4.4 Nor is there any reason to find, without further examination, that Rhône Poulenc cum suis have no action on the ground of the tenor of art. 16 EEX and/or the jurisdiction rule of section 54 of the French Act of 1984.

4.5 Next, Pharmachemie cum suis question what they call the "expediency of judging the substance of the case". On this ground they move that the claims be dismissed.

In explanation of this position Pharmachemie cum suis allege that the Dutch court should decline jurisdiction in favour of its French counterpart. This defence, which amounts to the invocation of the doctrine of forum-non-conveniens, is not correct. The EEX does not leave room for the application of this doctrine. Consequently, there are no reasons why the court should not give judgment on the substance of the present case.

Pharmachemie cum suis have not alleged that the Dutch court may not issue interim injunctions which will have to be executed (partially) in another Contracting State. As Rhône Poulenc cum suis have rightly alleged, applications for such injunctions have been granted in a number of cases, often with reference - explicit or otherwise - to the judgment of the Supreme Court in the case of Interlas v. Lincoln (judgment of 24 November 1989, NJ 1992, 404). There is insufficient reason to deviate from this ruling in the present case.

4.6 In the present interim injunction proceedings Pharmachemie cum suis are not disputing that under French law the activities in France of defendants 2 to 5 inclusive infringe the rights of Rhône Poulenc S.A. under the CCP. This means that in principle the injunction forbidding infringement as sought under a. is admissible.

Pharmachemie cum suis have alleged, however, that such an injunction forbidding infringement should not be issued since the CCP is void, or at any rate stands a real chance of being held to be void by the competent French court.

4.7 This defence is successful.

According to the criterion that is used by the Dutch courts, an injunction forbidding infringement must be denied, also considering the further circumstances, if there is a serious and not negligible chance that the patent will be nullified by the court judging the case on the merits. It may be assumed that a French court will be considerably more easily inclined to deny an injunction against infringement on the ground of possible nullification. This can be inferred indirectly both from the small number of applications for an interim injunction forbidding infringement (twelve applications between 1984 and 1990 and two after the scope of interim injunction proceedings was extended at the end of 1990, while the average number of procedures on the merits is 150 per year) and from the low rate of success of such applications (three injunctions granted). This contrasts sharply with the Dutch situation, where the number of interim injunction procedures exceeds the number of procedures on the merits (contrary to the situation in France it is not required that a procedure on the merits be pending) and where the "success rate" is well over 60%.

Consequently, the court assumes that an injunction should be denied if the nullification of the CCP by the French court cannot be entirely excluded. This is the case here. There are two reasons for this.

(1) It cannot be denied that the argument of Rhône Poulenc cum suis is more convincing than the "legal opinion" of the French lawyer Bruno Quint which has been submitted by Pharmachemie cum suis. Nevertheless, this opinion cannot simply be called incorrect and set aside, among other things because the interpretation favoured by Rhône Poulenc cum suis may be contrary to the intention of the system (Quint, page 2 last paragraph but one) and because it is not clear to which patents or parts of the patents the relative AMMs (Autorisations de Mise sur le Marché) relate (Quint, end of page 2 and page 3). For a judgment of these two issues a greater understanding of the circumstances in which the system was created and of the contents of the two patents and the AMMs in question, respectively, is required.

(2) A second reason (in the terminology of Rhône Poulenc cum suis "circumstantial evidence") is the fact that Rhône Poulenc cum suis did not, as would have been natural since there was no serious defence to the accusation of infringement, apply to the competent French court in order

to obtain an injunction, even though a procedure on the merits had already been commenced. This is an indication that Rhône Poulenc cum suis also believed that the French court would find that an injunction against infringement should be denied.

The conclusion is that the injunction against infringement claimed in paragraph a. must be refused.

4.8 The above reasons do not mean that it has been established that there is question of infringement of a valid patent, so that it cannot be established either that Pharmachemie obtained Ketoprofen Retard PCH 200 unlawfully. So the claims under b to d inclusive must be refused as well.

5. Judgment of claims e to h inclusive

5.1 The point at issue in claims e to h inclusive in fact concerns a dispute between SKF as the proprietor of a trademark and Pharmachemie as importer and distributor of Ketoprofen. Therefore, only these parties will be referred to in the following.

5.2 At the court hearing Pharmachemie declared expressly that it withdrew its plea of the lack of jurisdiction of the Hague President and moreover admitted that part of the injunctions sought would have to be executed in the district of The Hague, so that the President had jurisdiction pursuant to art. 37A, first paragraph, of the Uniform Benelux Trademarks Act (BTA).

5.2 (sic!) Pharmachemie has not disputed that in principle it is possible to use a combination of colours as a distinctive mark for the origin of goods, including medical drugs in the form of capsules.

Pharmachemie has alleged, however, that in the past ten or more years the common practice in the medical drugs branch has been for the manufacturers of drugs protected by patents (the branded drugs) to use a colour combination that is specific for the drug. Frequently, this colour combination is not registered. After the expiry of the patent rights the manufacturers of generic drugs bring the same product on the market for which they invariably use the colour combination of the proprietor of the branded drug, without the latter taking action. The background of this procedure is that the colour combination serves as an indication for the user that the drug is a certain kind of preparation (i.e. that the

generic product contains the same active agent as the branded drug). Generally, the origin of the drug is indicated by the use of a word trademark on the capsule, the blister strip and the blister packaging. That is indeed what appears to have been done in the present case.

On the ground of this allegation, against which SKF has put forward a defence that is insufficiently supported by facts and for which further proof has been put forward at the court hearing in the form of the oral statement of the director of Pharmachemie, Mr Looff, it is assumed in the present proceedings that currently it is common practice in the medical drugs branch to use similar colour combinations for drugs having a similar composition, so that the colour combination does not or no longer serve to distinguish the goods of an enterprise.

5.3 The conclusion is that SKF cannot invoke its Benelux registration against Pharmachemie, so that the claims e. to h. inclusive which are based thereon must be dismissed.

6. The costs of the proceedings

Since all claims will be dismissed, the plaintiffs must be condemned to pay the costs of the present proceedings.

7. The judgment

The President, giving judgment in interim injunction proceedings,

Dismisses the claims.

Condemns the plaintiffs to pay the costs, assessed on the part of the defendants up to this decision at NLG 5000.-- in fees and disbursements.

Declares the award of costs provisionally enforceable.

Thus given by H.J. van den Hul and pronounced in public at the court hearing of 5 January 1993 in the presence of the judge's clerk.

(signed) Th.S. Widmer (signed) H.J. van den Hul