Practical Pharmaceutical Patent Strategies 22 - 24 April 1998 Successful practical strategies for obtaining injunctions in France

FRANCE

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I. Patent infringement proceedings

1.1. Discovery

A key difference between French and common law judicial systems lies in the evidentiary process.

There is no discovery process in France.

Each party decides which evidence is worth producing.

As a result, the plaintiff cannot ask the defendant to produce information relating to the infringing product or process.

Likewise, the alleged infringer cannot ask the plaintiff to produce prior art: he has to search himself for the information he needs to challenge the validity of the patent.

The use of witnesses or expert witnesses is exceptional.

To enable the plaintiff to collect the necessary material to prove infringement, the French Industrial Property Code (article L 615-5) provides the patentee with the infringement seizure ("saisie contrefaçon").

1.2. How to obtain evidence - seizure orders

1.2.1. What is infringement seizure?

The infringement seizure does not consist in an injunction.

It mainly permits a visit of the alleged defendant's premises by a bailiff, ("huissier"), a public officer, whose statements are deemed authentic.

The public officer can be accompanied by a policeman, a patent agent chosen by the patentee, a photographer, an accountant or any other person whose skills may be useful (e.g. a computer expert if the seizure is directed toward information stored in a computerised information system).

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The public officer writes down the description dictated by the patent agent of the infringing device.

He can take photos or video, if appropriate, look into the accountancy books, review the technical and commercial documents and make copies of the relevant documents.

The public officer can also buy samples.

1.2.2. How to get an order for an infringement seizure?

The infringement seizure has to be authorised by the presiding Judge of the local Court of First Instance ("Tribunal de Grande Instance").

For this purpose, counsel for the patentee drafts and files a petition defining the exact scope of the authorisation requested.

Typically, the petition indicates:

- the persons authorised to assist the public officer (a policeman, a patent agent chosen by himself, a photographer...),
- the acts the public officer is authorised to perform (to be shown a machine, accountancy books, technical and commercial documentation, to make copies of some documents, to operate a machine, to acquire some samples of the infringing product(s)...).

The filing of the petition is *ex parte* (the defendant is only informed of the Court order by the bailiff, upon his arrival to perform seizure).

Exceptionally, the Judge restrict the terms of the petition, for example by adding that the seizure has to be carried out by a given date, or conditioning his authorisation upon the deposit of a bond by the petitioner.

But, usually, especially when the terms of the requested order appear reasonable, the Judge does not modify the petition.

1.2.3. Protection of confidential information

It happens that the seized party objects to the seizure of some information alleged to be confidential.

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In most cases, the dispute is solved by the appointment by the Court of an expert who is commissioned to listen to the parties and to sort out which documents (even confidential) are necessary to prove the infringement and which are not.

13. Schedule of events from the complaint until the trial

• The plaintiff must serve a complaint on the alleged infringer within 15 days from the date of the infringement seizure.

Failure to serve such complaint makes the seizure void.

- The plaintiff has the complaint recorded in Court; a Judge in charge of supervising the progress of the proceedings is appointed; this Judge will fix the dates of the different steps of the proceedings, which are referred to hereafter:
 - The plaintiff produces evidence to support his complaint.
 - The defendant files an answer, which may include a counterclaim, and produces evidence to support his contentions.
 - The parties pursue their exchange until they consider the discussion exhausted, which means, practically, until one party does not ask to reply; the Judge has also the power to declare the exchange closed.
- The case is argued in Court.

For patent cases, the trial usually takes place between one to three years after the filing of the complaint.

The final oral hearing lasts between two hours and a whole day (2 days in exceptional cases) according to the difficulty of the issues.

The Court is a panel of three Judges, who are always professional Judges; there are no jury in civil cases.

This hearing consists of two speeches: first the statement of the plaintiff's counsel and, afterwards, the statement of the defendant's counsel.

The Judges can ask questions or make comments if they wish to, but usually they intervene very little. There is no examination of witnesses or experts. Usually, the parties are not invited to give explanations to the Court.

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1.4. Motion for preliminary injunction

The preliminary injunction was introduced in French Patent Act of January 2, 1968 by an amendment of June 27, 1984.

Since a further amendment of November 26, 1990, the conditions for a preliminary injunction are, under article L 615-3 of Intellectual Property Code:

- 1. A prompt infringement suit: the plaintiff has to sue the alleged infringer without delay after he has become aware of the alleged infringement. The critical period of time seems to be, according case law, about six months.
- 2. Likelihood of success on the merits, which implies that neither the validity of the patent nor its infringement appear seriously challengeable.

Preliminary injunctions were not frequently granted until recently (less than 10 times since the change in Patent Act, in 1984). However there are some signs that the Courts are now more likely to grant it.

1.5. Costs

France is not a country where the justice is very expensive by comparison with common law countries.

Since there is no discovery process, the preparation of the case for trial is far less time consuming.

The trial itself is much shorter since there is no witness or experts examination.

The costs of a patent infringement case in France are usually only a fraction of the costs of the same litigation in common law countries.

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II. Some figures



Ministry of Justice Statistics (averages 1990-1995)

Tribunal de Grande Instance	Opened	Closed	Average duration (months)
Paris	172	158	14,7
Lyon	32	27	25,0
Rennes	19	14	13,7
Lille	9	10	24,1
Bordeaux	9	4	13,3
Strasbourg	9	7	13,5
Marseille	8	7	17,4
Nancy	6	7	16,9
Toulouse	6	5	28,5
Limoges	2	2	37,7
Other tribunaux de grande instance	68	62	15,5
Total whole of France	339	303	16,4

This table summarises the data communicated by the French Ministry of Justice which, every year, centralises statistics on the activity of each French court.

The title of the category shown is "claims brought for patent infringement and/or for unfair competition."

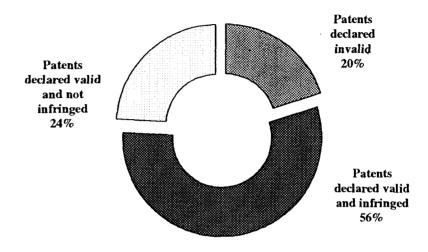
It shows the number of new cases, closed cases and also the average duration (in months) of proceedings and gives rise to the following remarks:

- very large predominance of the Paris Tribunal de Grande Instance which is seized of more than half the cases
- the Paris court is followed -well after- by the Lyon Tribunal de Grande Instance and then the Rennes Tribunal de Grande Instance
- the other 7 courts handle less than 10 cases per year
- this raises the question of whether the number of courts having jurisdiction should be restricted
- it is perhaps surprising to note the number of cases brought before the "other courts" which do not have jurisdiction over such cases: is this a sign that practitioners have poor knowledge of the rules relating to jurisdiction? or that files are categorized erroneously?
- The notion of average duration bears little meaning in practice insofar as the statistics make no distinction between cases which are closed following the delivery of a judgement and those which are closed as a result of being struck off at administrative level.

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Validity and infringement



This chart shows the outcome of the decisions of the Paris Tribunal de Grande Instance for the **294** cases judged on the merits at first instance level between 1990 and 1996 and which concerned **339** patents (some cases involve more than one patent).

The patent is declared invalid in 20 % of cases.

It is declared or admitted to be valid, but not infringed in 24 % of cases.

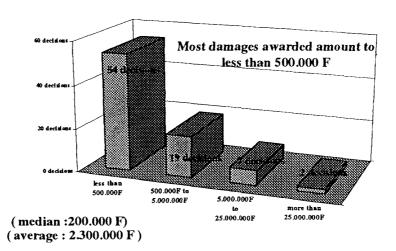
Infringement cases are therefore accepted in 56 % of cases.

We were not able to examine whether European patents come out better or worse after trial, as there were not enough cases to enable us to make any serious comparison.

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Amount of damages



82 decisions of the Paris Tribunal de Grande Instance ruled about damages.

This account does not include those decisions which awarded only provisional damages.

However, it includes both:

- decisions which fixed the final amount of damages without any expert opinion, when the court believed to have enough elements to enable it to do so,
- decisions which fixed the amount of damages after an expert opinion.

Accordingly, when we compare these 82 decisions to the number of decisions ruling upon infringement (± 300), we see that only 25 to 30 % of cases result in the final assessment of damages.

The bulk of cases are undoubtedly terminated through out of Court settlements or given up (for example following bankruptcy of the parties).

The amounts awarded are self explanatory: only 9 decisions out of 82 awarded more than 5.000.000 F.

The median line (as many decisions above as below) is situated at 200.000 F.

The average reaches 2.300.000 F only as a result of the most severe judgements.



Damages: hit parade

CIBA GEIGY et RHONE POULENC	
AGROCHIMIE / INTERPHYTO	40 333 800 F
GACHOT / MECAFRANCE	33 000 000 F
HK INDUSTRIES / FICHET BAUCHE	15 600 000 F
STEP / COSTER	11 000 000 F
COLOPLAST / HOLLISTER	9 500 000 F
HERRIAU / FRANQUET, MATROT, MOREAU	8 606 000 F
VISCORA VISKASE / VISCOFAN	7 994 000 F
PRODEL / RENAULT AUTOMATION	6 800 000 F
VAN DER LELY / REMAC	6 500 000 F
THEVENIN et FAYNOT / BORNES ET BALISES	4 716 000 F

Juagement	Fartes	Source	Damages
TGI PARIS (CH.03), 1994-03-04	CIBA GEIGY (Swiss company), CIBA GEIGY (SA) at RHONE POULENC AGROCHIMIE (SA) / INTERPHYTO (SA), LAUREAU (Me) at CHAVANNE de DALMASSY (Me)		40 333 800 F
PARIS (CH.04), 1990-10-18	GACHOT (SA) / MECAFRANCE (SA)	PIBD 1991 493 III 69, PIBD 1988 434 III 227	33 000 000 F
PARIS (CH.04),1992-07-07	HK INDUSTRIES (Sie) / FICHET BAUCHE (SA)		15 600 000 F
PARIS (CH.04),1992-07-08	SOCIETE TECHNIQUE DE PULVERISATION (SA) (STEP) / COSTER (SARL) et COSTERTECHNOLOGIE SPECIALI SpA (Italian company)		11 000 000 F
PARIS (CH.04),1991-11-12	COLOPLAST (SA) ET COLOPLAST AS (Sié de droit danois) / HOLLISTER INCORPORATED (American company)	PIBD 1992, \$19, III-194, PIBD 1990, 478, III- 324, ANN, 1992, N 2, PP. 206-212, Note de P. MATHELY;DB, 1992, N 2, (INTEGRAL);D, 1993, SOM COM par J-M. MOUSSERON et J. SCHMIDT, P. 377	9500 000 F
PARIS (CH.04), 1990-07-12	HERRIAU (STE) / FRANQUET (GILBERT), MATROT (STE), MOREAU (SA), Me LEMERCIER et Me WIART (representing the creditors of the company MOREAU)	PIBD 1990 490 III 704, PIBD 1987 419 III 351	8 606 000 F
PARIS (CH.04),1993-03-04	VISCORA (SA) (VISKASE) et VISKASE CORPORATION (Ste de droit américain) / VISCOFAN (Ste de droit espagnol)	PIBD 1993 547 III 414, PIBD 1991 510 III 629	7 994 000 F
TGI PARIS (CH.03),1995-06-29	PRODEL (Jacques) et PRODEL (Ste) / RENAULT AUTOMATION (Ste)		6800 000 F
TGI PARIS (CH.03), 1996-06-26	C. VAN DER LELY NV (Dutch company) et LELY INDUSTRIES (Dutch company) / MACCHINE AGRICOLE REMAC SRL (Italian company)		6 500 000 F
PARIS (CH.04),1995-02-09	THEVENIN (Jean) et FAYNOT (SA, Ets) / BORNES ET BALISES (SA)		4716 000 F

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Damages awarded by US courts: hit parade

	Average (bench)	7 500 000 \$	45 000 000 F
14	CONSTRUCTION TECHNOLOGY / LOCKFORMER	17 628 700 \$	105 772 200 F
13	HOMES / MEDICAL COMPONENTS	17 693 989 \$	106 163 934 F
12	KEARNS / CHRYSLER	18 740 465 \$	112 442 790 F
11	CORNAIR / MATSUSHITA	21 629 706 \$	129 778 236 F
10	BROOKTREE / ADVANCED MICRO DEVICES	25 744 600 \$	154 467 600 F
9	PPG/AVCO	25 856 018 \$	155 136 108 F
8	MICRO MOTION / EXAC	26 231 006 \$	157 386 036 F
7	B&H / OWENS ILLINOIS GLASS	36 485 400 \$	218 912 400 F
6	SCHNEIDER AG/ SCIMED LIFE	45 132 427 \$	270 794 562 F
5	HUGUES AIRCRAFT / UNITED STATES	113 775 000 \$	682 650 000 F
4	3M / JOHNSON & JOHNSON	116 797 696\$	700 786 176 F
3	EXXON CHEMICAL / LUBRIZOL	128 787 339 \$	772 724 034 F
2	ALPEX COMPUTER / NINTENDO	208 268 418 \$	1 249 610 508 I
1	POLAROID / KODAK	873 158 971 \$	5 238 953 826 F

It is enlightening to compare the 10 highest awards of damages in France for the period 1990-1996 with those awarded in the United States during the same period.

Even if we take into account the size of the market which counts around 6 times as many consumers, and even if we exclude the POLAROID/KODAK case which even the Americans consider to be exceptional, the damages awarded in the United States are still considerably higher.

Indeed, even the average for judicial decisions without a jury, i.e. 7.500.000 \$ or 45.000.000 F, is greater than the highest amount ever awarded in France.

This cannot be entirely explained by the possibility for American Courts to award increased damages (which may be up to *treble damages*).

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Ancillary sanctions (averages)

n Publication 3 journals

n Total cost of publications 35.000 F

n Indemnity for costs 20.000 F

(maximum 150.000 F)

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III. Recent French case law of interest for pharmaceutical industry

• GENENTECH v. LILLY FRANCE

Court of Appeals of Paris - 30 May 1997 declares valid Genentech's patent on Human Growth Hormon.

FISONS v. EUROPHTA

High Court of Paris - 4 July 1997 states that regulatory approval is not per se an infringement.

• GNR PHARMA v. SCIENCE UNION and LABORATOIRES SERVIER

Court of Appeals of Paris - 16 January 1998

holds that clinical studies, when kept confidential, do not make tested product available to public.

• ALLEN & HANBURYS v. SCAT

High Court of Paris - 30 January 1998

holds that a French SPC can rely on a regulatory approval which is not the first one.

• WELLCOME FOUNDATION v. PAREXEL

High Court of Paris - 6 March 1998

dismisses request for interim injunction against clinical tests designed to compare various ways of use of the patented product (aciclovir).

• ALLEN & ANBURYS v. PROMEDICA and CHIEST FARMACEUTICI

Court of Cassation - 24 March 1998

confirms that regulatory approval is not *per se* an infringement (note: in France, regulatory approval does not require delivery of samples).