

Post-Grant modifications of patent claims

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POST-GRANT LIMITATION OF A FRENCH PATENT BEFORE FRENCH / EUROPEAN PATENT OFFICES

- It has been possible to obtain a centralized limitation by amendment of the claims in all Contracting States where a European patent has been granted, since **December 13, 2007** (entry into force of **EPC 2000**).
- **Before August 4, 2008**, the only possibility of post-grant limitation of a French patent was provided by art. L.613-27 of French CPI in connection with partial nullification of a French patent.
- The patentee has the obligation to present a new claim wording to the French Patent Office, limited in accordance with the decision of the Court.
- The new claim can be rejected by the French Patent Office in case of non-compliance with the partial nullification decision of the Court.

THE LEGAL TEXTS

- France (IP Code)
 - Art L.613-24 introduction of the proceedings
 - Art L613-25 judicial sanction
 - Art L614-12 Revocation of European patents
 - Art R613-45 organization of proceedings

- EPO (EPC)
 - Art 105 bis et ter
Introduction of the proceedings
 - Rule 92, 94 The Request
 - Rule 93 precedence of opposition
 - Rule 95 Conditions
 - Art 138 (2) and (3) partial revocation
 - Art 105 quarter and Rule 96
Publication

Limitation proceedings before the INPI (the French Patent Office) in accordance with Article L.613-24 and L.613-25

- Application to French national patents
- Application to the French part of European patents
 - Article 2 (2) European Patent Convention (EPC):

"European patents shall, in each of the Contracting States for which they are granted, have the effect of and be subject to the same conditions as a national patent granted by that State, unless this Convention provides otherwise"

Limitation proceedings before the INPI (the French Patent Office) in accordance with Article L.613-24 and L.613-25

- The INPI has never expressed the slightest doubt regarding the application of this limitation proceeding to the French part of a European patent, despite any potential difficulties
 - CA Paris, 1 July 2011, Teva c. INPI and Eli Lilly: *“the reference made in Article L.614-12, to Article 105a of the Munich Convention is illustrative and does not in any way prejudice the jurisdiction of the Director of the INPI”*:
 - i. Primacy of the opposition proceedings

E.g.: Termination of proceedings and reimbursement of the fee R.93(2) EPC

- ii. Implications of Article L.614-17 CPI, which stipulates that the authentic text in France is that of the patent drafted in the language of the proceedings before the EPO (European Patent Office)

Would the INPI agree to consider restricted claims, drafted in German or English?

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Limitation proceedings before the INPI (the French Patent Office) in accordance with Article L.613-24 and L.613-25

- iii. Concurrency of two national and centralized limitations.
- iv. Checking of a current proceeding by the INPI, Article 105 (a) EPC; possibly by consulting the European Patent Register online
- v. Conversely, no option for the EPO to check a proceeding currently before the INPI
- vi. Appraisal of exceptions to patentability Art. 53c) EPC (dosage regimen)

INPI statistics

Request on limitations on the French part of European patents (EP/FR) or on national French Patent (FR)

YEAR	Type of patent		Main technical area			Total
	EP/FR	FR	Mecanical	Electronic	Chemistry	
2009	4	14	7	0	11	18
2010	7	14	7	2	12	21
2011	9	16	12	6	7	25
2012	5	4	4	1	4	9
2013 (until 15/10/2013)	8	13	7	2	12	21

INPI statistics

Request on limitations on the French part of European patents (EP/FR) or on national French Patent (FR)

	Total	Approved
YEAR		
2009	18	15
2010	21	20
2011	25	24
2012	9	6
2013 (until 15/10/2013)	21	11

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Average duration of the ACCEPTANCE OF LIMITATION

- INPI approx. 3 months
- EPO approx. 1 year

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Challenge by Patentee of a decision to refuse the limitation

- Outside the judicial process :

Art L.411-4 IPC: Appeal before the Paris Court of Appeal
+ French Supreme court

- As part of a legal proceeding :

- the trial judge has the jurisdiction to rule on the total/partial nullity of the object of the claim in question;

- A separate appeal may also be brought before the Paris Court of Appeal

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CHALLENGE BY A THIRD PARTY OF THE ACCEPTANCE OF LIMITATION

- Outside the judicial process: prove the interest in taking legal action
- In the event of invalidity or infringement proceedings, the judge will decide whether, following limitation, the extent of the scope conferred by the patent has been increased (Art L.613-25 d) IPC)
- Assessment of a limitation that would extend the scope of the claim reserved for the invalidity court :
 - CA Paris, 30 March 2011, Teisseire c. INPI and Routin and
 - Supreme Court, 30 May 2012, Routin v/ Teisseire,

CHALLENGE BY A THIRD PARTY OF THE ACCEPTANCE OF LIMITATION

- CA Paris, 1 July 2011, Teva c. INPI and Eli Lilly, again for failing to prove the interest in taking legal action.

“[...] is reserved for the knowledge of the patent invalidity judge the case in which the alleged limitation of a claim would produce its extension[...] the means developed in appeal may effectively be analyzed as an argument for patent invalidity opposed in the context of an infringement action [...]”.

- Inadmissibility of the appeal before the Paris Court of Appeal (1 July 2011, Teva c. Eli Lilly) brought while an invalidity legal action is pending.

“[...] inadmissibility of the appeal insofar as it is asking the court to rule on the validity of claims that are subject to a pending invalidity action before the Paris Tribunal de Grande Instance”

WHEN CAN THE REQUEST BE PRESENTED?

- At any time after issue, and until after lapse of the patent
- Several times, but pay attention to Art L613-25 in fine
- The first time in appeal, article 564 of the CPC
 - Paris Court of Appeal, 30 November 2011, ADA c. Emicela :

“the request [for partial invalidity only], that seeks only to defend the industrial property title on which the infringement action is based, by challenging the full annulment of the asserted claims, may not be deemed a new request under Article 564 of the Civil Code of Procedure”.

Note : Settlement agreement, deferral and reinstatement of the patent limited under appeal (Paris Court of Appeal, decision dated April 11, 2012)

- CA Paris October 30, 2013 Astellas v. Mylan :

The appeal court is accepted to stay until the decision of the French Patent office about the limitation requested after the nullification of the patent in first instance.

LIMITATION PROCEDURE (a few special terms and conditions required)

- Agreement of the licensee,
- Approval of all the co-owners,
- Conformity to Article L. 612-6 IPC (clarity and basis of the description), and, especially,
- Does the amendment to the claim correspond to a limitation of the patent's scope?

INTERPRETATION OF THE CONCEPT OF LIMITATION

- Article L.613-24 § 1: limiting the scope of a patent by amending its claim(s)
- Interpretation of the term « limitation » in the EPO's review Directives (Part D- Chapter X - §4.3 (a reduction in the scope of the protection conferred by claims))
- Be attentive to any limitation of the subject of the claim that could hide an extension of the scope of the right conferred by said claim

Example 1

Granted claim

- P — copolymère — P

with P= polar terminal groups

And Molar % of P < 10 %

Description

- P are polar terminal groups, in particular alcoholic and/or carboxylic groups, and more particularly alcoholic groups.

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Example 1

Limited claim

P— copolymère — P

With molar % of alcoholic groups < 10 %

Example 1

- Presumed patent infringement
 - 8 % alcoholic groups (-OH)
 - 7 % carboxylic group (-CO-OH)

Example 1

	Infringement	
Granted claim	8% OH + 7 % -COOH = 15 % polar groups	NO
Limited claim	8% OH + 7 % -COOH = 15 % polar groups But < 10% OH	YES

Example 2

- Granted claim

Catalyst constituted by an association of Pt-Ni on a zeolite with

$$1\% \leq \text{Ni} \leq 10\% \text{ and } \text{Ni}/\text{Pt} < 10$$

- Description

$$\text{Ni}/\text{Pt} < 5 \text{ (limited preferred ratio)}$$

- Limited claim :

$$\text{Pt-Ni with } 1\% \leq \text{Ni} \leq 10\%$$

$$\text{Ni}/\text{Pt} < 5$$

Example 2

Presumed Infringement Pt 1,5% and Ni 1,5%

Granted claim

Limited claim

$0,1\% \leq Pt \leq 1\%$

$0,2\% \leq Pt \leq 2\%$

Infringement NO

Infringement YES

Example 3

- Granted claim

Bituminous concrete comprising a mixture of a mineral granulate and a binder containing 10% of fibers.

- Prior art

Binder for bituminous concrete which contains 5, 10 and 15 % of glass fibers

- Limited claim based on description
10% elastomeric fibers

Example 3

- Presumption of Infringement

Binder with 10% of a powder of elastomeric resin

- Infringement by equivalence if technical function is protected ?

Example 4

- Art L.614-13

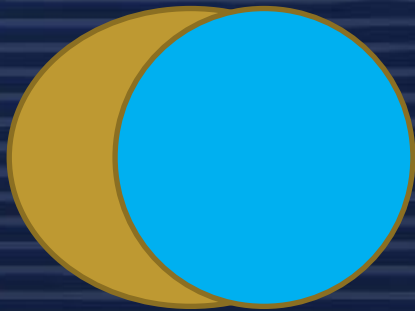
Where a French patent covers an invention for which a European patent has been granted to the same inventor or to his successor in title with the same filing date or the same priority, the French patent shall cease to have effect at either the date on which the period during which opposition may be filed against the European patent expires without opposition having been filed or the date on which the opposition proceedings are closed and the European patent maintained.

....

The subsequent lapse or annulment of the European patent shall have no effect on the provisions of this Article.

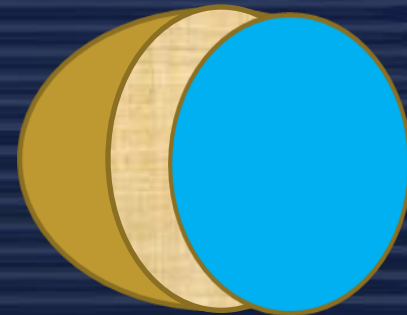
Example 4

- Annulment does not affect the situation
- What about Limitation ?



French patent

EP patent



Resurrection ?

Art L615-17

Annuities ?

Limited EP patent

Limitation based solely on the descriptive elements

- SYNGENTA case

- Limitation refused by INPI
- Limitation refused also by the Appeal Court (7/09/2011)
- Supreme Court of 19 March 2013

It needs to be established whether the subject of the amended claim was disclosed directly and unambiguously in the patent description.

- 2nd Court of Appeal dated October 25, 2013
 - Limitation found word for word
 - Review of patentability or sufficiency of disclosure unrelated to the limitation proceedings;
 - Therefore exclusive of any extension of acts of infringement and violation of third-party rights.
- New appeal (filed by INPI) pending before the Supreme Court
 - Contributory infringement ? (Art L.613-4 French CPI)

Limitation based solely on the descriptive elements

- BOEHRINGER INGELHEIM Telmisartan case, CA Paris September 11, 2013
 - Link to issues concerning the definition of products to be protected by a SPC (Supplementary Protection Certificate) – identify the ECJ (European Court of Justice) ruling that defines the concept of products covered by the basic patent, i.e. a product mentioned explicitly in the wording of the claims.
 - Appeal before the Supreme Court pending ?
- Limitation taken in the description approved by the INPI and validated by the Paris TGI, on 11 July 2013 (Phitech case)
- Limitation taken in the description approved by the EPO and validated by the Paris TGI, on 20 September 2013 (Koninklijke Philips Electronics NV)

A few special cases that have not yet been fully decided

- Limitation of the claim by the introduction of a characteristic that leads to the exclusion from patentability (Article L.611-16)
- Possibility of :
 - correcting any clear errors, EPO review Directives, Part D-Chapter X);
 - deleting a characteristic in a dependant claim
 - changing the claim category
 - combining an independent claim with only a part of a dependant sub-claim
- Research report or documentary opinion to be reconsidered, in the event that the research has not covered a characteristic "framed" in the description
- Problem of introducing a disclaimer insofar as Article L.612-6 stipulates that claims shall be based on the description (Decision TGI Toulouse March 17, 2011 Vincience case, confirmed by the Appeal Court)

A few special cases that have not yet been fully decided

- Limitation of a divisional application that leads to a situation involving double protection but considered inadmissible means as the prohibition of the double protection is not deemed grounds for invalidity under Art. 138 CBE (Paris TGI, March 15, 2013)
- The addition of a characteristic could be considered as a limitation, but the deletion of another existing characteristic would necessarily lead to an extension (Paris TGI, January 24, 2013).
- Limitation to disregard grounds for insufficiency of disclosure

Right to intervene on behalf of third parties (Observations)

- **Before the INPI :**
 - The INPI does not publish the filing of the limitation request, but a voluntary registration is possible (Paris TGI, 21 October 2011, Ateliers LR Etanco c. SFS Intec)
 - Third parties informed via notification of the limitation request by the patentee, or legal action brought against a suspected infringer,
 - Observations taken into account and transmitted to the patentee.
- **Before the EPO :**
 - Information immediately put on the Register;
 - Acceptable: « patentability observations » of Art 115 EPC shall be interpreted widely including aspects related to Art. 84 and 123(2) EPC (Directive before the EPO: part D – Chapter X-5 §4.5)
- **Before the Appeal Court :**
 - Inadmissible third parties to intervene in an action brought before the Paris Court of Appeal by the patentee against a decision to refuse the limitation (Actavis v. Boehringer CA Paris September 11, 2013)

CONSEQUENCES

- Limitation under a legal action: in principle **stay of proceedings**
 - Order of 9 July 2010, Routin c. Teisseire, stay of proceedings (with the parties' approval) during review of the action brought before the Court of Appeal.
 - Paris Court of Appeal, 21 October 2010, Ateliers LR Etanco c. SFS Intec: *the decision taken by the Executive Director of the Institut National de la Propriété Industrielle will govern the outcome of these proceedings insofar as the limited patent shall henceforth be deemed the subject of the action seeking invalidity.*
 - Order issued by the Paris Court of Appeal, 19 January 2012, Trikon c. Alcatel Vacuum: *the decision by the INPI will influence the throughput before the court, which is hearing an appeal to overturn the above-mentioned ruling, insofar as the limitation application brought before the INPI proposes to amend the disputed patent.*
 - Paris TGI, 7 April 2009, Georgia-Pacific c. Delipapier: *when the FR part of an EP patent is subject to an infringement action, limitation proceedings brought before the EPO lead to a stay in proceedings until the EPO's decision.*
 - Paris Appeal Court 30/10/2013 Astellas Pharma c. Mylan

but ...

CONSEQUENCES

- Appeal Court of Paris June 8, 2012
Boehringer (Telmisartan +HCTZ)
 - Stay of proceedings refused
 - Lateness of the limitation request
 - Lack of cause based on proper administration of justice

Confirmed by Supreme Court 13/12/2013

CONSEQUENCES

.../...

- Acceptance of disclaimers
 - Toulouse TGI, 17 March 2011, Vincience c. Institut Européen de Biologie Cellulaire: *the validity of the limitation of an EP patent by means of a disclaimer is assessed with regard to the latest EPO case law; in this case, the subject of the disclaimer is disclosed in the application, there is no infringement of Art. 123(2) and the subject of the patent is not extended: the limitation is valid.*
- Retroactive nature of the limitation on the date of filing the patent application,
- No effect on the seizure for counterfeiting
 - Lyon Court of Appeal, 13 July 2011, Lapiere, Lesage c. Décathlon, Promiles : *the limitation (filed after the appeal) has a retroactive effect, it is the limited patent that is deemed the subject of the action seeking invalidity. However, the limitation has no effect on the enforceability of the seizure for counterfeiting brought before the first instance.* .../...

CONSEQUENCES

.../...

- Publication that makes the limitation effective:
 - in France publication in the French National Patents Register (Registre National des Brevets),
 - in Europe publication in the European Patent Journal (Bulletin Européen des Brevets) with republication of an amended leaflet : B3
- Article L.613-25
 - new grounds for invalidity
 - possible limitation currently under judicial review
- Risk of abuse of process
 - Appeal Court of Paris October 18, 2013 (PIBD n°997 III.1)

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EXAMPLE OF A LIMITATION ACCEPTED BY THE EPO

- EP 984 957 B1, Esomeprazole case
 - Granted Claims :
 - Claim 1. The magnesium salt of S-omeprazole trihydrate .
 - Claim 9. A pharmaceutical composition comprising the magnesium salt of S-omeprazole trihydrate according to any of claims 1-4 as active ingredient in association with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients.
 - Description : Page 4, lines 33 and 34 : “Examples of such active ingredients include, but are not limited to anti-bacterial compounds, non-steroidal anti-inflammatory agents, antacid agents, alginates and prokinetic agents.”

EXAMPLE OF A LIMITATION ACCEPTED BY THE EPO

- EP 984 957 B3
 - Limited claims :
 - The magnesium salt of S-omeprazole trihydrate.
 - [...]
 - 9. A pharmaceutical composition comprising the magnesium salt of S-omeprazole trihydrate according to any of claims 1-4 and a non-steroidal anti-inflammatory agent as active ingredients in association with a pharmaceuticall acceptable carrier.”
 - Amended description :
 - Additional paragraph [25] :
 - “According to another aspect of the invention there is provided a pharmaceutical composition comprising the magnesium salt of S-omeprazole trihydrate and a non-steroidal anti-inflammatory agent as active ingredients in association with a pharmaceutically acceptable carrier.”

EXAMPLE OF A LIMITATION ACCEPTED BY THE EPO

- CENTRAL LIMITATION BEFORE EPO

- Limitation request : May 8, 2012
- Mention of the decision to limit published on September 18, 2013
- CCP filing date : August 1, 2012
- CCP FR 12C0046 for “Association of magnesium salt of S-omeprazole trihydrate with acetylsalicylic acid”.

⇒ In this way, the UK High Court of Justice raised among others the following questions to the ECJ *Actavis v. Boehringer*, September 23, 2013.

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Questions to be referred to the ECJ (Case C-577/13)

- The patent could be amended so as to include such a product combination claim ?
- Can a patent that has been amended after the grant of the patent and either (i) before and/or (ii) after grant of the SPC be relied upon as the « basic patent in force » ?
- Is it necessary to consider whether the combination of active ingredients A and B is a distinct and separate invention from that of A alone ?
- Does the SPC regulation prevent the competent industrial property office to enable
 - (a) suspension of the prosecution of SPC...in order to allow the applicant to apply for amendment of the patent
 - (b) recommencement at a later date once the amendment has been granted
 - Deadline ?
 - 6 months from the date which valid MA, or
 - Or 6 months of the date of which the request for amending the patent.



Thank you for your attention !

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