

Presumption Of Patent Validity In Patent Litigations – The New Trends

**11th EGA Legal Affairs Forum –
March 27, 2015**

Kristof Roon, Partner,
Crowell & Moring

Contents

- A. *“Prima facie”* validity of patents in BE
- B. Traditional approach
- C. The new case law
- D. Conclusion: Towards a less strict approach?
- E. Developments in other jurisdictions
- F. What about the UPC?

A. "Prima facie" Validity Of Patents In BE

- Very important question: impacts the strategic question clearing the way or launch at risk?
- Presumption that a European patent/SPC is *prima facie* valid for the purpose of obtaining a preliminary injunction (PI) and seizure proceedings
- Therefore, invalidity defenses raised by the alleged infringer are very unlikely to succeed

BUT, following recent case law, the *prima facie* validity of patents in PI proceedings is not "untouchable" anymore...

B. Traditional Approach

Supreme Court, Jan. 5, 2012, *Novartis v. Mylan*
(« Fluvastatin »):

- It is irrelevant that the EPO Opposition Division revoked the patent since the appeal against that decision before the EPO Technical Board of Appeal has suspensive effect (the patent is presumed valid until the final outcome)
- Therefore, a European Patent (EP) remains *prima facie* valid even after revocation by the EPO Opposition Division (“administrative body”)

B. Traditional Approach (2)

Supreme Court, June 24, 2013, *Lundbeck v. Eurogenerics*
(« Escitalopram »):

- A PI could be granted pending the appeal, notwithstanding the 1st instance finding of invalidity by a court (on the merits)
- A patent invalidated by a 1st instance decision can still be considered a legal basis for granting a PI (the decision has no force of *res judicata*)
- Clearing the path is not an option

Brussels Court of Appeal, March 15, 2013, *Bayer v. Sandoz*
(« Drosperinon »):

- A PI granted prior the invalidity decision in 1st instance proceedings on the merits automatically remains in effect notwithstanding the invalidity of the patent, as long as the 1st instance decision is under appeal

C. The New Case Law

Supreme Court, June 26, 2014, *AstraZeneca v. Sandoz* (“Quetiapin”) and *Bayer v. Sandoz* (“Drosperinon”)

- Following an invalidity finding at 1st instance, the PI comes to an immediate end, but a new PI is possible if the patentee demonstrates with sufficient certainty that (i) the appeal against the first instance decision will be successful and (ii) the PI is necessary in all the circumstances of the case, including the likely length of the proceedings and the scale of potential damages

Supreme Court, Sept. 12, 2014, *Syral v. Roquette* (“Maltitol”)

- If protective measures are requested, the judge must, when assessing the *prima facie* validity of a patent, also take into account final judgments in another EU jurisdiction (UK and France) invalidating the patent
- The legal force of a foreign judgment (Brussels I Regulation) may even create a presumption of invalidity in relation to the Belgian part of the EU patent?

C. The New Case Law (2)

First applications:

- Pres. Comm. Brussels (Seizure), November 21, 2014, *AZ v. Sandoz* (“Quetiapin”)
- Pres. Comm Brussels (PI), Dec. 9, 2014, *Novartis v. Mylan* (“Rivastigmine”),
- Pres. Comm. Brussels (PI), March 24, 2014, *AZ v. Teva* (“Quetiapin”):
AZ did not sufficiently demonstrate that its appeal would be successful. Benefit for the patient and the social security was taking into account when balancing the rights of the parties.

D. Conclusion: Towards A Less Strict Approach?

- Presumption of validity is still the starting point
- Patentee cannot simply rely on the suspensive effect of the appeal filed against the invalidity decision given by a national court or an administrative body (EPO)
- Belgian judges will have to make an assessment of the validity of a patent invoked in PI or seizure proceedings « *taking into account all facts and circumstances invoked by the parties relating to the validity of the patent* ».
- Foreign judgments have to be taken into account when assessing the prima facie validity of a (EU) patent

E. Developments In Other Jurisdictions

FRANCE (Article L 615-3 of the IP Code): Divergence in Courts

- **First Instance Court (TGI) of Lyon, July 21, 2008:** “The judge [...] is not required to perform a thorough and in-depth analysis of the validity of the asserted patent, which is a matter to be determined by the court ruling on the merits”.
- **In TGI Paris, ord. réf., Oct. 3, 2012, SA Sanofi v. Teva Santé:** The judge considered that the referral to the CJEU in parallel UK proceedings did not preclude the grant of the requested PI in France
- Practice at the Court of Appeal of Paris (experience with French prosecution and statistics)

Developments in other jurisdictions (2)

UNITED KINGDOM:

- PI's are difficult to obtain: arguable case and irreparable harm
- **Court of Appeal, *Novartis AG v. Hospira UK Limited* [2013] EWCA Civ 583:** Decision on the granting of a PI in respect of UK patents which are under appeal, notwithstanding the patents previously being held invalid in first instance proceedings by the trial court. However, the circumstances in which such a PI may be granted are limited to where the invalidity decision has been appealed, and it can be shown that the appeal has a real prospect of success

Developments in other jurisdictions (3)

GERMANY:

- If the asserted patent is not attacked (by an invalidity action or an opposition) the PI will be granted (provided that there is urgency and infringement);
- If the patent is under attack, the court will look at the merits of the invalidity attack:
 - A PI will only be granted if the court is convinced that the patent survives the attack. This is usually the case, if the patent already survived contradictory proceedings (e.g. an opposition). Other indications might also help to convince the court (foreign decisions with regard to the same patent; licensing to competitors etc.).
 - If the patent has not yet survived contradictory proceedings and other evidence for its validity is not available it is usually not a suitable basis for a PI.

Developments in other jurisdictions (4)

GERMANY (2):

- In generic cases the courts are usually more generous, since a generic launch might destroy the market for the patentee. Even though the patent has not yet survived contradictory proceedings the court might grant a PI, if it is more likely than unlikely that the patent survives the pending invalidity attack. This usually requires an analysis of the best invalidity arguments by the PI court and a prognosis regarding the merits of these attacks.
- If there is a first instance decision that invalidates the patent and appeal is pending, it is usually not possible to obtain a PI until the first instance decision is overruled (except *Olanzapin*).

Developments in other jurisdictions (5)

OTHER JURISDICTIONS:

- **The Netherlands:** no presumption of validity ; is there a reasonable change of success that the patent will be invalidated in the proceedings on the merits?
- **Sweden:** strong presumption of validity ; foreign decisions do not play an important role (unless there is a very clear tendency towards invalidity)
- **Denmark:** Unless clear-cut novelty destroying arguments are invoked, there is a strong presumption of validity (this might change in light of the new court system)
- **What about the UPC?**

UPC

UPC-agreement:

- **Article 62.2:** The Court shall have the discretion to weigh up the interests of the parties and in particular to take into account the potential harm for either of the parties resulting from the granting or the refusal of the injunction.
- **Article 62.4:** The Court may, in respect of the measures referred to in paragraphs 1 and 3, require the applicant to provide any reasonable evidence in order to satisfy itself with a sufficient degree of certainty that the applicant is the right holder and that the applicant's right is being infringed, or that such infringement is imminent.

UPC (2)

Rules of Procedure (17th draft):

- **Rules 101-110:** procedure
- **Rule 209.2:** 2. In exercising its discretion pursuant to Rule 209.1, the Court shall in particular take into account: (a) whether the patent has been upheld in an opposition procedure before the European Patent Office or has been the subject of proceedings in any other court
- **Rule 211.2:** In taking its decision the Court may require the applicant to provide reasonable evidence to satisfy the Court with a sufficient degree of certainty that the applicant is entitled to commence proceedings pursuant to Article 47, that the patent in question is valid and that his right is being infringed, or that such infringement is imminent.