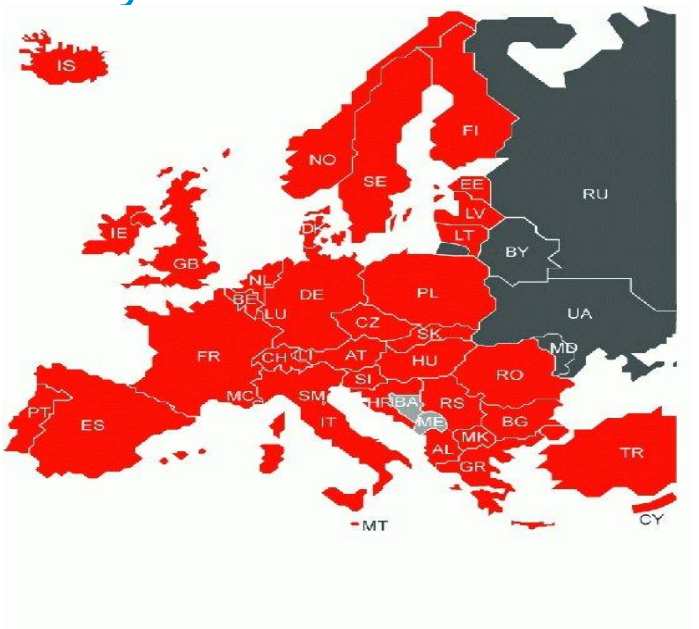
Europe Divided – Update on National Case Law in Europe

Leythem Wall

29 November 2011

European Patents

- 38 EPC Member States as of 1 January 2011
- Centralized prosecution
- Bundle of national patents



- Articles 69 EPC and 138 EPC - National Law ‘largely’ harmonized
- Theoretically, same results for parallel national proceedings

Dosage Regimes – G2/08

- **Question 1: Where it is already known to use a particular medicament to treat a particular illness, can this known medicament be patented under the provisions of Articles 53(c) and 54(5) EPC 2000 for use in a different, new and inventive treatment by therapy of the same illness?**
- *Answer: Where it is already known to use a medicament to treat an illness, Article 54(5) EPC does not exclude that this medicament be patented for use in a different treatment by therapy of the same illness.*
- **Question 2: If the answer to question 1 is yes, is such patenting also possible where the only novel feature of the treatment is a new and inventive dosage regime?**
- *Answer: Such patenting is also not excluded where a dosage regime is the only feature claimed which is not comprised in the state of the art.*
- **Question 3: Where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G 5/83.**
- *Answer: A time-limit of three months after publication of the present decision in the Official Journal of the European Patent Office is set in order that future applicants comply with this new situation.*

Dosage Regimes – G2/08

- The Enlarged Board of Appeal published their decision October 2010
- Dosage Regime is a distinguishing feature
- Article 54(4), (5) EPC and Article 53(c) EPC newly interpreted
- But… results in national proceedings are not entirely consistent

Activis v Merck

- Merck & Co. awarded EP0724444, filed 11 October 1994

- Claim 1 reads:

"The use of 17ß-(N-tert-butylcarbamoyl)-4-aza-5-alpha-androst-1-ene-3-one for the preparation of a medicament for oral administration useful for the treatment of androgenic alopecia in a person and ***wherein the dosage amount is about 0.05 to 1.0 mg****"*

- No European Opposition filed

- Revocation actions brought by Activis in national courts

Activis v Merck

- UK Court of Appeal (Civil Division) 21 May 2008, Case No. [2008] EWCA Civ 444, decided that a dosage regime was patentable and that, in the particular circumstance, it was novel and non-obvious
- German Bundespatentgericht on 26 June 2008, Ni 58/06 (EU) decided that a dosage regime was patentable (but that it was lacking novelty in the specific situation)
- French Tribunal de Grande Instance on 28 September 2010 decides that a dosage regime is not patentable because it is "plainly not" a second therapeutic application:

"A specific dosage for the treatment of an illness constitutes neither a first nor a second therapeutic application but simply an indication of the range within which this substance is efficacious so as to treat such or such an illness in light of the tests and research completed and explained in the patent."

Activis v Merck

- With direct reference to the Enlarged Board of Appeal Decision G2/08, the French court had the following to say:

"As rightly pointed out by the claimants, the French courts are not bound by the decisions of the EPO which is not a court (as opposed to the European Union courts' decisions which are binding to national courts) so that these decisions even issued by the Enlarged Board of Appeal are merely indications of the analysis made by the EPO to grant European patents."

Teva v Merck – 'Double Kill'

- Not a one-off decision
- Merck's patent again held invalid on 9 November 2010 by Tribunal de Grande Instance, this time upon Teva's request
- Oral arguments in Teva case took place on **27** September 2010, the day before the Activis decision
- According to French rules of proceedings, the court must make its decision on basis of when the oral arguments are exchanged. New situation arising after this exchange cannot be taken in consideration

Mepha v Merck

- Other EPC jurisdictions appear to be following G2/08
- Merck awarded EP1175904, relating to the use of alendronic acid in the treatment of osteoporosis, by oral administration of **10mg once a day**
- On 29 March 2007 the Swiss generic companies Mepha Pharma AG and Mepha AG brought a proceeding before the Commercial Court of Zurich
- The Commercial Court held that the only feature likely to confer novelty on claim 1 was the dosage regime. They concluded that the dosage regime was a method of therapeutic treatment and thus excluded from patentability
- Merck appealed the decision to the Swiss Federal Supreme Court
- In light of G2/08 the Swiss Supreme Court on 4 March 2011 reversed the decision of the Commercial Court

The Inescapable Trap

- Added Matter is a ground of Opposition
- Claim broadening not permitted – “The Inescapable Trap” (G1/93)
- Added feature can be removed if it makes no technical contribution
- National Laws are closely aligned, including the German Patent Act:

- Section 21 (1) - extension of subject matter beyond the content of the patent application as originally filed is not allowed

- Section 22 (1) – post grant amendment leading to extension of scope of protection is not allowed

An Escape Route

- German Federal Supreme Court ruled on 21 October 2010, (Xa ZB 14/09) that ***an added feature may remain*** in the claim if it serves to specify (restrict or limit) a feature disclosed as part of the invention in the original application
- DE195 49 795 nationally opposed and maintained on appeal in amended form with addition in the patent specification that claim 1 contain features not to be considered for patentability. Added matter question referred by Patent Court to Supreme Court
- The question of whether an added feature renders a claim invalid depends on whether the feature results in a ***different invention*** than the one originally disclosed (‘*aliud*’)
- Section 21(1) does not account for cases in which the necessary deletion of an originally non-disclosed feature from a claim would create a new reason for revocation of an unallowed extension of the scope of protection of a granted claim
- No rights may be derived from the ‘added matter’, e.g. cannot be used to distinguish from the prior art

Intermediates

- Intermediate products are substances that during a chemical process are generated by one step and used for the succeeding steps
- Intermediate products are patentable under the EPC (**T 22/82**, **T 163/84**, **T 648/88**, **T 1239/01**)
- Guidelines for Examination C-IV 7.3 specify unity of invention requirements for applications having claims to intermediates:

- the intermediate and final products have the same essential structural element
- the intermediate and final products are technically inter-related, i.e. the final product is manufactured directly from the intermediate or is separated from it by a small number of intermediates all containing the same **essential** structural element

Intermediates

- Court of Turin on14 January 2011 ruled in Bayer Schering Pharma v Industriale Chimica Srl that **intermediates are not patentable**
- Patent in question claimed a process for the production of drospirenone. It also expressly claimed the intermediate “Idrox”
- Previous Italian Supreme Court decision (ruling no. 11094/1990) over a patent on cimetidine found that intermediates were not patentable
- Court of Appeal of Milan in November 1993 considering another case involving the same cimetidine patent reasoned in favour of patentability of intermediates*:*

“If it is true that a product, in order to result in patentable subject matter, must satisfy a human need, there is no reason for excluding that such a goal be performed where a new and inventive product has a function that is purely instrumental to an industrial production process”

- In this case however the Court of Turin followed the Supreme Court ruling stating that the intermediate is not patentable per se as it does not have ***“an autonomous function and a utility that can conceptually be separated from the process of synthesis which conducts to the production of drospirenone”***

Old Belgian Recipes

- On 20 January 2011 the Commerical Court of Ghent revoked the Belgian patent on “speculoospasta” held by biscuit manufacturer Lotus Bakeries
- Speculoospasta is a bread spread based on crushed caramel cookies that took the Benelux market by storm, outselling Nutella two-to-one
- Success of the spread was increased by Belgian television show “The Inventors”. Two participants presented virtually identical speculoos-based bread spreads, and although one participant held a patent on the bread spread, Lotus Bakeries decided to commercialize the spread of the other participant
- Lotus Bakeries began a media offensive claiming the patent of the other participant wasn’t valid. Patentee was a much smaller entity than Lotus Bakeries and so settled, including transfer of the patent to Lotus Bakeries in 2009
- Immediately after acquiring the patent, Lotus Bakeries invoked the patent against competitors, while in 2009 generating revenue of over 10 million EUR

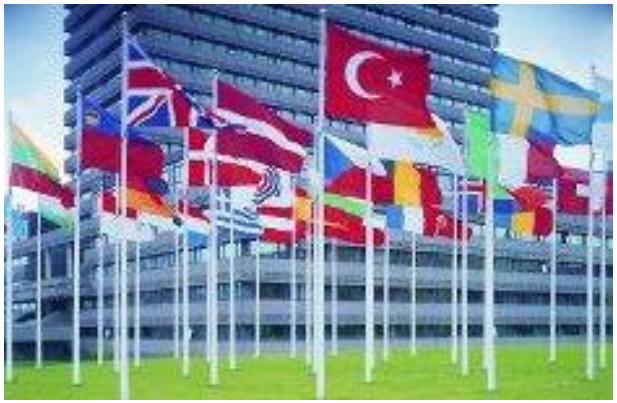
Old Belgian Recipes

- Speculoos manufacturer Biscuiterie Willems initiated revocation proceedings
- The legal battle lasted two years, involving:

- counterfeit search & seizures by Lotus Bakeries

- Biscuiterie Willems seeking evidence from the editor of a small website in the north of the Netherlands, getting affidavits from the US and holding tastings of spreads and pies by judges

- The patent was nullified because the Court decided that it was not new as its substance was already disclosed in an old recipe for a speculoos-cake
- The Court also commented that the commercial behavior of Lotus Bakeries was “opportunistic”, but that even this “textbook example of lack of sustainable commercial ethics” had to be tolerated in a free market economy



THANK YOU