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COMPARATIVE ANALYSIS OF THE PROTECTION OF NEW DOSAGE REGIME CLAIMS

(France, Germany the United Kingdom, the Netherlands and Italy)

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Table of Contents

1 Summary 3

2 Situation in France 4

3 Situation in Germany 6

4 Situation in the United Kingdom 7

5 Situation in the Netherlands 9

6 Situation in Italy 10

1 Summary

Whereas the current position of the French Patent Office and the French courts are not very patent-friendly for dosage regime claims of a medicinal product, the German, UK and Dutch courts allow for the patentability of such dosage regime claims, following the principles set out by the Enlarged Board of Appeal of the EPO in its decision G2/08 of 19 February 2010. On the contrary, the Italian courts have not yet issued any official position on this sensitive issue.

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2 Situation in France

Will the new dosage regime claims for medicinal products, granted by the European Patent Office, be enforceable in France?

French latest news as to the new dosage regime claims for medicinal products: the dismissal of a preliminary injunction, based on Article L. 615-3 of the French Intellectual Property Code (in short, *"IPC"),* on the ground that the validity of a dosage regime claim is seriously challenged, in that it cannot be considered as a patentable second medical use in virtue of Article 54(5) of EPC, insofar as it has not been defined a new technical effect or a new benefit related to it.

By a decision of 23 June 2014 handed down by the Judge managing the case (in Gédéon v Mylan), the French Judge upholds its earlier case law according to which a dosage regime claim cannot benefit from the exception to the rules on exclusion of patentability of methods of therapeutic treatment, by stressing that a dosage regime claim is patentable only on the condition that this dosage regime fulfils a new technical effect or provides a new benefit for the patient.

That was not the case in the present court case, since the subject-matter of the opposed claim was the administration of the same dosage regime, but in a single dose (1.5 mg) instead of two doses (0.75 mg) with a time difference of 12 hours (for the same indication, emergency contraception), without explaining the technical advantage provided other than *"the comfort of taking the dose once daily which does not achieve a technical effect"*.

Then the Judge holds that the objection of lack of novelty is serious, in that the opposed legal means aims at establishing that this is a mere dosage regime claim, excluded from patentability as being a method of therapeutic treatment which is not patentable.

This decision is fully in line with the earlier decisions rendered on the merits by the Paris first-instance court (*"Tribunal de Grande instance de Paris")* in *Actavis Group v Merck Sharp & Dohme* (3rd Chamber, 1st Section, 28 September 2010, judgment not final), taking into account the qualification of a method of therapeutic treatment not patentable, and in *Teva v Merck Sharp & Dohme* (3rd Chamber, 1st Section, 9 November 2010), holding the insufficiency of disclosure, on the ground that the therapeutic effect should have been verified, whereas the specification does not evidence that some trials or experiments have been conducted in order to prove the therapeutic effect related to the claimed dosage regime.

More recently, in a court case *Eli Lilly v Daiichi* (Division 5, Chamber 1, 12 March 2014), the Paris Court of Appeal holds that some dependent claims, relating to specific dosage regimes (in this case, for raloxifene) were invalid for lack of inventive step insofar as those dosage regimes were determined by the doctor prescribing this medicinal product to his patient with a broad range of spectrum (from 0.1 to 1000 mg) without explaining the relevance of these dosage regimes.

Similarly, and more recently, in a court case *Akzo Nobel v Teva, Ratiopharm, Merckle & Gemelogs-BRS* (3rd Chamber, 1st Section, 5 December 2014, judgment

not final, in this case for a Progestagen-only contraceptive, 70 to 80 micrograms of desogestrel), the Paris first-instance court affirmed its case law, according to which a dosage regime claim would not be patentable, as it would be part of a method of therapeutic treatment, since *"the medical prescription and the dosage of medicinal products would be an essential part of the activity of the doctor. The determination of a dosage, as a full part of a therapeutic process is therefore excluded from protection by patent"*.

Thus the current trend of French case law is to consider that dosage regime claims are invalid for grounds of different nature, on a case-by-case basis, exclusion from patentability as being considered a method of therapeutic treatment, for insufficiency of disclosure or for lack of inventive step.

It should, however, be stressed again that the Enlarged Board of Appeal of the European Patent Office, in its decision G2/08 of 19 February 2010, has recognized the patentability of a claim of which the only featured claimed, which is not comprised in the state of art, is a dosage regime (*"a single dose before bedtime"*), as soon as it is new and involves an inventive step.

Therefore the analysis of these decisions shows that, for obtaining, in France, an efficient protection of the dosage regime claims, such as granted by the European Patent Office, it is necessary to take certain precautions when drafting the specification of the patents at issue, notably by sufficiently characterizing in the patent specification the new technical effect or the new benefit related to the claimed dosage regime and, also by disclosing the trials or experiments enabling to support this new technical effect or this new benefit thereof.

However the difficulty certainly resides in the fact that, when filing the European patent application, these pieces of information are rarely available because the development of the medicinal product is still at its early stages and, then, the trials and experiments are not sufficiently advanced.

Otherwise, it must be emphasized that all the commented decisions relate to a European patent and, notably, the French designation of this European patent.

The situation is different in France for French patent applications, comprising dosage regime claims, which are filed with the French Patent Office (*"INPI").*

Indeed the current position of the French Patent Office is to issue notifications before rejection for any dosage regime claims.

Therefore the only way for obtaining a protection for the dosage regime of a medicinal product is to file a European patent application, designating France, and have it granted in view of the favourable case law of the Enlarged Board of Appeal of the EPO; the French designation of this European patent will then take effect in France and might be enforceable … if fortunately, in case of patent litigation, the trend of the French courts, related to the validity of such dosage regime claims, becomes more patent-friendly and concerned of the interests of the patent holders.

3 Situation in Germany

German Case Law, on new dosage regime claims, applies the principles set out by the enlarged board of appeal of the European Patent Office.

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In the matter G 2/08 of 19 February 2010, the Enlarged Board of Appeal of the EPO decided that pharmaceuticals that are already in use for the treatment of a certain disease, may be patented again for the same disease even if the only feature that was formerly not included in the state of technology is a dosage regime.

In its decision, the EPO considered the patentability of a dosage regime in terms of a second further medical indication pursuant to Article 53(c), Article 54(5) of the European Patent Convention (*"EPC"*), to be generally permissible.

Initially, the Federal Patent Court (*"Bundespatentgericht"*) did not follow the requirements of the EPO and denied patentability of a pharmaceutical on the basis of a dosage regime on the grounds of lack of inventive activity (BPatG 14 W (pat) 13/09). The Federal Court of Justice (*"Bundesgerichtshof"*) repealed this decision, however.

The Federal Court of Justice instead expressly confirmed the line of jurisprudence established on a European level by the EPO (Federal Court of Justice X ZR 40/12 — *Fettsäuren*; BGH X ZB 5/13 and BGH X ZB 6/13 — *Kollagenase I und II*). In this respect, the decision of the Federal Court of Justice is based on the relevant parallel standards in terms of the European EPC — Article 54(5), i.e. provisions Section 3(4) of the Patent Act.

By extending the principles of patentability of pharmaceuticals to cases in which the regime not only concerns the dosage as such but also other modalities of application, that is, for example, the method of administration, the consistency of the substance, the group of patients or other parameters, the decision of the Federal Court of Justice, to some extent, goes beyond the European requirements (BGH X ZB 6/13).

In such cases, it is a condition that the objective purpose of the therapy-related instructions in question are to influence the effects of the substance, or the pharmaceutical itself — it is not intended that therapy-related instructions alone can be patented.

Therefore, by these decisions, the case law of the highest court in Germany continues to implement the European requirements. It is to be expected that the Federal Patent Court, too, will adjust its decisions to that effect in the future.

4 Situation in the United Kingdom

The UK intellectual property office and the UK courts allow for the patentability of new dosage forms of Pharmaceuticals.

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The position regarding the patentability of dosage forms of pharmaceuticals in the UK is set out in detail in guidelines published by the UK Intellectual Property Office (IPO)[1]. The relevant statutory provision is section 4A Patents Act 1977:

"4A Methods of treatment or diagnosis
(1) A patent shall not be granted for the invention of —
(a) a method of treatment of the human or animal body by surgery or therapy….
(…)
(4) In the case of an invention consisting of a substance or composition for a specific use in any such method, the fact that the substance or composition forms part of the state of the art shall not prevent the invention from being taken to be new if that specific use does not form part of the state of the art."

The effect of section 4A(4), which stems directly from Article 54(5) of European Patent Convention revised in 2000, is that a claim to a known substance or composition for a specific medical use is novel if the substance or composition has not previously been used for that specific purpose.

Prior to 2008, although *"Swiss-type"* claims[2] for second medical uses were generally granted by the IPO and allowed by the English courts, the practice of the IPO was to treat those claims which defined the new use in terms of the mode of administration or the quantity, frequency or timing of dosage only, as being not patentable, on the grounds that they were merely methods of treatment that lacked novelty over the prior use of the substance to treat the same disease. [3,4]

However, in the Court of Appeal decision in *Actavis v Merck*[5] in 2008, Jacob LJ held that a claim for the use of finasteride (a known drug previously used for treating prostate conditions) for the preparation of a medicine for treating alopecia, with a dosage much lower than that previously used for treating prostate conditions, was

[1] Examination Guidelines for Patent Applications relating to Medical Inventions in the Intellectual Property Office, May 2013 (http://www.ipo.gov.uk/medicalguidelines.pdf). See in particular paragraphs 92-93, 114-115, 124-137 and 173-175.

[2] "*Swiss-type claims*", so called due to first being allowed by the Swiss patent office, are claims for the use of compounds for the manufacture of medicaments for specified second medical uses, where the same compounds have previously been used in medicine for different purposes.

[3] Bristol-Myers Squibb v Baker Norton Pharmaceuticals [2001] RPC 1.

[4] Merck's Patents [Alendronate] [2003] FSR 498.

[5] Actavis UK Limited v Merck & Co Inc [2008] EWCA Civ 444.

not invalid for lack of novelty, applying the previous EPO decision in *Eisai*[6] in which it was determined that such *Swiss-type* claims were valid.

Since the *Actavis v Merck* decision, the position in the UK regarding the patentability of new dosing forms and methods of a known substance has been clarified: the UK adopts an approach consistent with the EPO Enlarged Board of Appeal in *Abbott Respiratory*[7]. Second medical use claims which are distinguished from the prior art solely by the dosage regime used, or the mode of administration, *are* considered patentable if the claimed use is both novel and inventive, with the proviso that if the claim is directed at the activity of the physician rather than the drug manufacturer, it may be objectionable under Section 4A(1)(a) Patents Act 1977, which precludes the patentability of methods of treatment of the human body by therapy.

[6] G5/83 *Eisai* [1985] OJ EPO 64.

[7] G 02/08 *ABBOTT RESPIRATORY/Dosage regime* OJ EPO 2010, 456.

5 Situation in the Netherlands

The Dutch District Court of The Hague allows for the protection of new dosage regime claims; it is likely to be confirmed by the court of appeal in The Hague.

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After EPC 2000 had entered into force, including its new article 54(5), comprising a purpose-related product protection for any further specific use of a known medicament in a method of therapy, no justified reason existed for the so-called Swiss-type claim. So it came without surprise when the Enlarged Board of Appeal of the European Office decided in its decision G 2/08, dated 19 February 2010, that the use of Swiss-type claims was no longer allowed. Instead the Enlarged Board decided that dosage regimes of known medical products could be patented if the claimed use should be considered new and inventive. So the Swiss-type form for second medical use claims was replaced by the so called "*purposed-limited product claims*", e.g. the format "*compound X for the use in the treatment of disease Y*", meaning that new dosage regimes on existing medicines could be patented.

Dutch courts tend to follow the leading case law of the European Patent Office (EPO). This means that under Dutch law, new dosage regimes are relevant technical features which should be taken into account when assessing novelty and inventive step.

This was confirmed in a recent decision of the District Court of The Hague, regarding the "*finasteride*"[8] 1 mg products[9]. Until now this decision has not been confirmed by a higher court, *e.g.* the Court of Appeal in The Hague. Nonetheless, considering that Dutch courts tend to follow the case law of the EPO, it is likely that also these higher courts will consider new dosage regimes as relevant technical features for the assessment of novelty and inventiveness.

[8] "*Finasteride*" in a dosage of 5 mg can be used to treat the enlargement of the prostate, "*Finasteride*" in a dosage of 1 mg can be used to treat male pattern baldness

[9] IEPT 2014.04.23, Rb Den Haag, *MSD v Mylan*

6 Situation in Italy

New dosage of drugs under Italian jurisdiction, patentability and counterfeiting.

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The issue of patentability of pharmaceutical products on the sole ground of a different dosage regime has been thoroughly addressed at a European level. However, in Italy, case law on the matter is lacking, with the consequence that there isn't any official position yet.

Having specified the above, it is worth pointing out that both the legal framework and authors do offer a few insights on the topic at hand which should be taken into account.

In particular, pursuant to Article 46 of Legislative Decree No. 30/2005 (the "***Code of Industrial Property***"), concerning the "*novelty*" requirement for patentability, patents can be granted with respect to "*a substance or a combination of substances already included in prior art, provided that this is for the purpose of a new use*". Through said rule, Italian law allows the so called "*Swiss-type claims*", i.e. the patentability of known substances or combination of substances with respect to a medical use different from the use or uses covered by the preceding patents.

In light of the above, a few Italian authors suggest expanding the aforementioned rule so to include the patentability of drugs even when the inventive character concerns only the dosage regime and not also the treatment of different diseases.

Another issue worth considering is the one regulated by Article 71 of the Code of Industrial Property concerning dependent patents. According to said Article "*a compulsory license may be granted if the invention protected by a patent cannot be used without jeopardizing the rights of a patent granted based on a prior application. In such event, a license can be granted to the holder of the later patent in such a measure as to allow the same to exploit the invention, as long as the latter represents, compared with the object of the prior patent, a material technical progress having a substantial economic value. A license so obtained may not be assigned otherwise than together with the patent for the dependent invention. The holder of the main patent, in turn, has the right to be granted with a compulsory license on the patent of the depending invention, at reasonable conditions*". As a few authors pointed out, dosage patents should fall within the scope of such rule, with all the consequent limitations (for example, with respect to the payment of royalties); this is because such patents are achieved also thanks to the research and development of the originator company which patented the drug first: failing to do so would essentially grant companies patenting the sole dosage regime a sort of *"R&D free riding*". Indeed, the latter concerned patent, though granting a full exclusivity on the new product, derives not only from the research carried out by the patenting company with respect to the new dosage regime, but also from the R&D investments by the company who patented the pharmaceutical product first.

Lastly, pursuant to Article 68, paragraph (1), letter c (regulating the so called "*Galenic exception*"), the exclusive right granted by a patent does not extend "*to the*

extemporaneous preparation of drugs made in pharmacies, on a unit by unit basis and for prescription medications so prepared, as long as industrially made active principles are not used". The rationale behind the Galenic exception is balancing out the patent owner's right to exclusivity with the patient's right to health, a constitutionally guaranteed principle. In a recent decision (please refer to judgement No. 39187/2013), the Italian Supreme Court clearly outlined the limitations to the Galenic exception and ruled that the dosage regime plays a significant role in this perspective. More precisely, according to the Court, in addition to the requirements provided for by the aforementioned Article 68 and to the fact that the Galenic exception is applicable only when specific therapeutic reasons occur, in order to assess whether or not the chemist's conduct falls within the exception at issue, the different dosage of the drug extemporary prepared by the chemist must be considered as well: indeed, if the drug made by the chemist has the same dosage of the patented drug, the Galenic exception does not apply, on the contrary a counterfeiting case occurs.