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The Judgment of 12 March 2015 of the CJEU in Actavis v. BI: is the "subject-matter of the patent" test crafted by the AG in Medeva to replace the "core inventive advance" test?

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On 12 March 2015, the Court of Justice of the European Union ("CJEU") published the judgment announced in our last blog in Case C-577/13, in response to *some* of the preliminary questions referred by the High Court of Justice (England and Wales), Chancery Division (Patents Court) in a case between Actavis Group EHF, Actavis UK Ltd ("Actavis") and Boehringer Ingelheim Pharma GmbH & Co. KG. ("BI"). The facts of the case before the referring Court may be summarised as follows:

Background of the case:

On 9 August 1999, BI was granted a Supplementary Protection Certificate ("SPC") for Telmisartan based on a marketing authorisation for Telmisartan granted on 16 December 1998 and patent EP (UK) 502.314, granted on 20 May 1998.

On 19 April 2002, a second marketing authorisation was granted to BI for a combination of Telmisartan and hydrochlorothiazide ("HCTZ"), a diuretic that inhibits the kidneys' ability to retain water. On 6 September 2002, BI filed an application for an SPC for this combination, relying on the same patent and the second marketing authorisation. Since the "basic" patent only contained claims mentioning one of the combination's active ingredients (i.e. Telmisartan), the UK IPO suggested to BI to limit the claims of the "basic" patent so as to include a claim mentioning the combination of both Telmisartan + HCTZ. It should be noted, in passing, that the combination of an active ingredient such as Telmisartan in combination with HCTZ was explicitly described in the specification of the patent as granted. Following the UK IPO's suggestion, on 19 November 2003, BI filed an application to amend its patent, which was actually accepted by the UK IPO on 10 November 2004. After the "basic" patent had been amended, the SPC for the combination ("Combination SPC") was granted on 13 January 2005.

Actavis filed a revocation action against the Combination SPC, alleging that, at the date when the application for the SPC was filed (6 September 2002), the two members of the combination were not mentioned in the claims of the basic patent. BI defended the validity of the SPC, arguing that amending a patent is legitimate both under the European Patent Convention ("EPC") and under national law and that such amendments, if accepted, have retrospective effect.

Against this background, the referring Court decided to stay the proceedings and refer to the CJEU

four questions with a wide array of sub-questions, which focused on two points: (i) whether or not a patent amended after its granting can be relied upon as a "basic patent in force" for the purpose of fulfilling the conditions set out in Article 3(a) of Regulation (EC) 469/2009 ("The SPC Regulation"); and (ii) whether Article 3 (a) and (c) of the SPC Regulation "must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination. If that question is answered in the negative, the national court is also seeking to ascertain how the duration of the "Combination SPC" is to be determined, for the purpose of Article 13(1) of that regulation" (par. 25 of the judgment).

The judgment of 12 March 2015:

After having identified the two questions that the CJEU considered to be relevant, it noted that "it is common ground in the main proceedings that, in that combination, telmisartan, which is the innovative active ingredient of Boehringer's basic patent, is the sole subject-matter of the invention. Boehringer did not, in any event, contribute to the discovery of hydrochlorothiazide, which is a molecule within the public domain, and the claim relating to that substance does not constitute the subject-matter of the invention" (par. 26). This statement only makes sense if it is understood to mean that, in the main proceedings it was common ground that, in contrast to telmisartan, which was new, HCTZ was already known when the patent application was filed.

The CJEU then moved on to consider what "a patent which protects a product as such" means in the context of Article 1(c). It noted that, according to BI and the Portuguese Government, the mere fact that the two active ingredients are specified in the wording used in the claims would be sufficient for them to be considered as protected. As the readers will have noticed, this was the test actually applied by the CJEU in the judgment of 24 November 2011 (Case C-322/10 *Medeva*) and the saga of decisions that followed. In contrast, Actavis maintained that the protection should be extended only for the development of a product which is the "true subject-matter of the invention covered by the patent in question", that is, for its "technical contribution" or "core inventive advance." Here one can see the footprints of the "core inventive advance" test applied by the CJEU in par. 30 of the judgment of 12 December 2013 (Case C-443/12 *Actavis v. Sanofi*). In this judgment, the CJEU had added that "if a combination consisting of an innovative active ingredient in respect of which an SPC has already been granted and another active ingredient, which is not protected as such by the patent in question, is the subject of a new basic patent within the meaning of Article 1(c) of that regulation, the new patent could, in so far as it covered a totally separate innovation, confer entitlement to an SPC for that new combination that is subsequently placed on the market" (par. 42). Obviously, the reference to "a new basic patent" must be interpreted to mean "a new claim" (of a new patent or of the same patent), as it would not seem logical to require that other invention to be protected by a different patent. In addition to being illogical, such requirement would be easy to circumvent by filing a divisional application or a parallel application with the same priority date. And, perhaps more importantly, such requirement would have no legal basis in the text of the SPC Regulation.

Going back to the judgment of 12 March 2015, at par. 33, relying on par. 29 of its judgment of 12 December 2013 (Case C-443/12 *Actavis v. Sanofi*) and par. 30 of its judgment of the same date in case C-484/12 *Georgetown University v. Octrooicentrum Nederland*, the CJEU noted that "it is possible, in principle, on the basis of a patent which protects several different "products", to obtain

several SPCs in relation to each of those different products, provided, inter alia, that each of those products is "protected" as such by that "basic patent" within the meaning of Article 3(a) of Regulation No 469/2009, in conjunction with Article 1(b) and (c) of that regulation".

At par. 35, the CJEU continued to build on its judgment of 12 December 2013 (Case C-443/12 *Actavis v. Sanofi*), this time to reiterate the paragraph at par. 40 of the latter, where it noted that the objective of the SPC Regulation "is not to compensate the holder fully for the delay to the marketing of his invention or to compensate for such delay in connection with the marketing of that invention in all its possible commercial forms, including in the form of combinations based on the same ingredient".

Interestingly, from here on, the judgment of 12 March 2015, which has been written by the same Judge Rapporteur who wrote the *Actavis v. Sanofi* decision (Judge Camelia Toader), deviates from the wording used in her previous decision. At par. 36, instead of relying on whether or not the combination is a "core inventive advance" (par. 41 of the *Actavis v. Sanofi* decision, actually cited at par. 36 of the new judgment), the CJEU has now written that "if it were accepted that all subsequent marketing of an active ingredient in conjunction with an unlimited number of other active ingredients which do not constitute the *subject-matter of the invention covered by the basic patent* [emphasis added by the author] would confer entitlement to multiple SPCs, that would be contrary to the requirement to balance the interests of the pharmaceutical industry and those of public health as regards the encouragement of research within the European Union by the use of SPCs (see, to that effect, judgment in *Actavis Group PTC and Actavis UK*, EU:C:2013:833, paragraph 41)". Although, as mentioned, the new judgment does refer to par. 41 of its previous judgment, at par. 36 it uses a totally different wording. No reference to "core inventive advance" or "totally separate invention" will be found in the new judgment.

Construing from the previous findings, at par. 38 the CJEU has reached the conclusion that "in order for a basic patent to protect "as such" an active ingredient within the meaning of Articles 1(c) and 3(a) of Regulation No 469, that active ingredient must constitute the *subject-matter of the invention covered by that patent* [emphasis added by the author]. Trying to follow this logic, at par. 39 the CJEU gave the following answers:

"*In the light of the foregoing considerations, the answer to Questions 2 and 3 is that Article 3(a) and (c) of Regulation No 469/2009 must be interpreted as meaning that, where a basic patent includes a claim to a product comprising an active ingredient which constitutes the sole subject-matter of the invention, for which the holder of that patent has already obtained an SPC, as well as a subsequent claim to a product comprising a combination of that active ingredient and another substance, that provision precludes the holder from obtaining a second SPC for that combination.* "

Rather surprisingly, at par. 40 the CJEU added that:

"*Given that, in the main proceedings, the combination SPC cannot be regarded as an SPC granted in accordance with Regulation No 469/2009, there is no need to answer the last part of the third questioning, concerning the interpretation of Article 13 of the regulation, which determines the duration of an SPC*".

In this author's opinion, it was not for the CJEU but for the referring Court to decide – of course applying the test crafted by the CJEU – whether or not in light of the facts and evidence before the

referring Court, the combination SPC can be granted.

This is because determining whether or not an invention constitutes "the subject-matter of the invention covered by that patent" requires determining the scope of protection of that patent, a competence that corresponds to national Courts. This was highlighted by the CJEU at par. 40 of its judgment of 12 December 2013 in Case C-493/12 *Eli Lilly v. HGS*:

"*40. […] The court cannot, therefore, provide further guidance to the referring court concerning the manner in which it is to determine the extent of the claims of a patent issued by the EPO*".

Therefore, at par. 40 of its recent judgment of 12 March 2015, the CJEU simply invaded the competences of the referring Court.

Comment:

In its recent judgment of 12 March 2015, the CJEU has omitted any reference to the concept of "core inventive advance" used in its previous judgment of 12 December 2013 (Case C-443/12 *Actavis v. Sanofi*) and has proposed a test based on whether or not the "product as such" (e.g. a combination) constitutes "the subject-matter of the invention covered by that patent". The only way of reconciling the "subject-matter covered by the invention" test with the "core inventive advance" test would be to understand "subject-matter covered by the invention" to mean "core subject-matter disclosed". But the problem of this approach is that rather than interpreting the judgment, it would require altering what the judgment actually states. For example, the judgment uses the term "covered" instead of "disclosed." In addition, if the CJEU had meant to apply the same test as in *Actavis v. Sanofi*, it would simply have used the same wording. And as mentioned, the new judgment, which has been drafted by the same Judge Rapporteur, from par. 36 on has abandoned the "core inventive advance" wording used in its previous judgment. On another note, in some of its judgments, by requiring the research that the SPC is meant to compensate to be reflected in the basic patent, the CJEU appears to lose sight of a very fundamental point: SPCs were not conceived to compensate the research carried out *before* the patent application was filed only, but also the research carried out *after* the patent application was filed. This is why the time that the SPC is meant to compensate is the time lost *after* the patent application was filed.

Going back to the "subject-matter of the invention covered by the patent" test, this test is not new at all, as it was already proposed by Advocate General Verica Trstenjak at par. 68-70 of her Opinion of 13 July 2011 in Case C-322/10 *Medeva BV v. Comptroller-General of Patents, Designs and Trade Marks*. In particular, at par. 68-69, she wrote that:

"68. Nor is that conclusion altered in any way by the discussion conducted in the main proceedings in the context of Article 3(a) of Regulation No 469/2009, on the distinction between the subject?matter – or extent of protection – and the protective effect of the basic patent. That debate concerns, in particular, the question whether the fact that an active ingredient which is the subject?matter of a patent is an integral part of a combination of active ingredients and, as a consequence, that entire combination of active ingredients may not be produced or placed on the market without the consent of the patent proprietor (that is the protective effect of the patent) implies that the combination of active ingredients is deemed to be protected by a patent in force.

69. The decisive consideration in that context is the fact that the definition of the basic patent in Article 1(c) of Regulation No 469/2009 takes as its basis the subject?matter of the patent, and not its protective effect. A basic patent within the meaning of Regulation No 469/2009 must therefore

be understood as one whose subject?matter comprises either a product as such, a process to obtain a product or an application of a product within the meaning of Article 1(b) of Regulation No 469/2009."

Interestingly, the only place in the SPC Regulation where the concept of "subject-matter" of the patent is used, is in the title of Article 4 ("Subject matter of protection"). For in patent law, the concept of "subject-matter" of the patent is not a usual concept. If it has to be given any meaning, it would refer to the subject-matter covered by the scope of protection of the patent, as opposed to the "disclosed" subject-matter, for example, which is of course a much narrower concept, with the "core inventive advance" concept being much narrower. But no matter how unusual the "subject-matter" test might be, unlike the other tests used by the CJEU in the past, it does seem to have some basis in the text of the SPC Regulation, although, for the purpose of interpreting article 3(a), it does not appear to take us any further that the seminal judgment of 16 September 1999 (Case C-392/97 *Farmitalia Carlo Erba Srl*).

Going back to the Opinion from Advocate General Trstenjak, at par. 70 she highlighted quite rightly that:

"*In the absence of harmonisation of patent law in the European Union, the question whether a product as such, a process to obtain a product or an application of a product within the meaning of Article 1(b) of Regulation No 469/2009 forms the subject?matter of a national or European patent must, as Union law now stands, be answered on the basis of the national rules governing that patent. Nevertheless, the definition of the basic patent laid down in Article 1(c) of the Regulation requires that, in the application of that definition, regard is always had to the subject?matter of the patent in question, and not to its protective effects."*

In other words, it is for the national Court to determine whether or not a product (in the case at hand, a combination) "forms the subject-matter of a national or European patent", applying the national rules governing that patent, although applying the "subject-matter" test coined by the CJEU. The Opinion from Advocate General Trstenjak in that case further confirms that, at par. 40 of its recent judgment of 12 March 2015, the CJEU blatantly invaded the territory reserved to national Courts.

All in all, the latest stumbling block placed by the CJEU in the bumpy road taken by applicants who wish to try to amortise the vast resources invested in developing new medicinal products appears to have abandoned the "core inventive advance" test and replaced it with the "subject-matter covered by the patent" test. Let's hope that the new test sticks around for at least a day or two…

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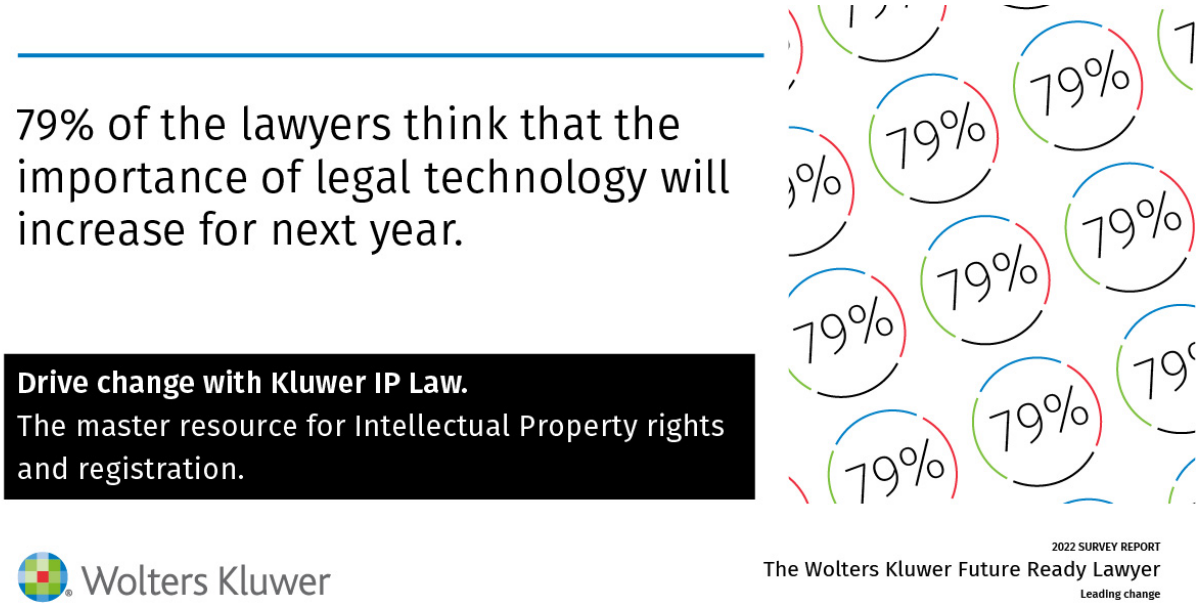

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