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Barcelona Court of Appeal publishes most surprising Judgment on pharmaceutical patents, the role of the CJEU, and Art. 70.7 of TRIPS

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1. Introduction:

Over the last decade, in some of the countries that did not introduce patent protection for pharmaceutical products until 1992, there has been an intense debate which has included, inter alia, the following two questions: (i) whether or not under Articles 70.2 and 27.1 of TRIPS, a patent *granted* following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but *granted* solely in relation to the process of manufacture, does, by reason of the rules set out in Articles 27 and 70 of TRIPS, have to be regarded from the entry into force of that Agreement as covering the invention of that pharmaceutical product; and (ii) whether or not Article 70.7 of TRIPS obliged WTO Member States to permit the modification of patents that were *pending* when TRIPS came into force to claim the enhanced protection (i.e. the product) introduced by TRIPS.

For readers' benefit, it should be recalled that Article 70.7 of TRIPS reads as follows.

“7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are *pending* on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.”

2. The Judgment delivered by CJEU on 18 July 2013 (Daiichi):

As the readers will know, in its Judgment dated 18 July 2013 (Case C-414/11 *Daiichi Sankyo Co. Lt et altri v. DEMO*) the CJEU gave a negative answer to the first question. The patent application was filed on 20 June 1986 and the patent was granted on 21 October 1986, i.e. almost 10 years before TRIPS came into force. In this context, the Greek Court asked the CJEU the following question:

“(3) Under Articles 27 and 70 of the TRIPS Agreement, do patents covered by the reservation in Article 167(2) of the [EPC] which were *granted* before 7 February 1992 that is to say, *before the above agreement entered into force*, and concerned the invention of pharmaceutical products, but which, because of the aforementioned reservation, were granted solely to protect their production process, fall within the protection for all patents pursuant to the provisions of the TRIPS Agreement and, if so, what is the extent and content of that protection, that is to say, have the pharmaceutical products themselves

also been protected since the above agreement entered into force, or does protection continue to apply to their production process only, or must a distinction be made based on the content of the application for grant of a patent, that is to say, as to whether, by describing the invention and the relevant claims, protection was sought at the outset for the product or the production process or both?”

It should be clarified that the question contains a typo, since TRIPS did not come into force in “1992” but in “1995”, as correctly explained in § 16 of the Judgment.

In view of these background facts, the CJEU gave the following answer to the question asked by the Greek Court:

“3. A patent *obtained* following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but *granted* solely in relation to the process of manufacture, does not, by reason of the rules set out in Articles 27 and 70 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, have to be regarded from the entry into force of that agreement as covering the invention of that pharmaceutical product.”

3. The two Rulings given by the CJEU on 30 January 2014:

In January 2014, the CJEU handed down two new decisions in which it simply reiterated the same answer already provided in its previous Judgment of 18 July 2013. The reason is quite simple: the Greek Court had asked the exact same question:

“(3) Under Articles 27 and 70 of the TRIPS Agreement, do patents covered by the reservation in Article 167(2) of the [EPC] which were *granted* before 7 February 1992 that is to say, *before the above agreement entered into force*, and concerned the invention of pharmaceutical products, but which, because of the aforementioned reservation, were granted solely to protect their production process, fall within the protection for all patents pursuant to the provisions of the TRIPS Agreement and, if so, what is the extent and content of that protection, that is to say, have the pharmaceutical products themselves also been protected since the above agreement entered into force, or does protection continue to apply to their production process only, or must a distinction be made based on the content of the application for grant of a patent, that is to say, as to whether, by describing the invention and the relevant claims, protection was sought at the outset for the product or the production process or both?”

It was indeed rather odd for the Greek Court to pose the same question about the situation of patents already *granted* before the TRIPS came into force, because the patent on the Greek Court’s table in these two new cases had not been *granted* (i.e. they were *pending*) when TRIPS came into force. However, this was of course for the Greek Court to assess. According to the CJEU case law interpreting Article 267 of the TFEU, the CJEU must confine itself to answering the specific questions asked by the referring Court. It is the latter’s responsibility to assess the relevance of the question in the context of the factual and legal framework of the dispute before the national Court.

Therefore, although the patent on the Greek Court’s table was *pending* when TRIPS came into force, the CJEU was under the obligation to answer the specific question asked by the Greek Court which, for reasons that only the Greek Court will know, did not mention *pending* patents but *granted* patents.

That is why, when explaining the “LEGAL CONTEXT”, the CJEU did not make the slightest reference to Article 70.7 of TRIPS, either in the Judgment of 18 July 2013 or in the two Rulings of 30 January 2014. As it was irrelevant to the (same) question asked by the Greek Court in the three cases, in its three decisions the CJEU omitted the citation of paragraph 7 of Article 70 by way of inserting suspension

points [...]:

“In Part VII of the TRIPs Agreement, ‘Institutional arrangements; final provisions’, Article 70, ‘Protection of Existing Subject Matter’, provides:

‘1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement.

...”

4. The Judgment delivered by Barcelona Court of Appeal on 22 October 2014:

A) The CJEU would have answered a question that the Greek Court did not ask:

In view of the text of the question referred by the Greek Court, I am sure that readers will understand the surprise caused by a Judgment dated 22 October 2014 published last Monday, in which Barcelona Court of Appeal reached the conclusion that, in its two Rulings of 30 January 2014, the CJEU would have provided an answer to the second question announced at the beginning of this blog, i.e., whether or not Article 70.7 of TRIPS obliged WTO Member States to permit the modification of patents that were *pending* when TRIPS came into force to claim the enhanced protection (i.e. the product) introduced by TRIPS.

Clearly, the CJEU could not have provided an answer to that question simply because it was not asked by the Greek Court in the first place.

B) The Judgment attributes to the Greek Court a question that it did not ask:

On page 29, the Judgment stated that:

“Although the scope of such decision may cast some legal doubt, given that, in our opinion, the facts involved in the Rulings dated 30 January 2014 have notable differences compared to the facts involved in the Judgment dated 18 July 2013, the objective fact is that, the Court having asked about the protection that the TRIPS Agreement confers on a patent applied for when the Reservation to the EPC was in force and prior to the entry into force of such Agreement, and granted thereafter with product and process claims, the Court replies as follows: *“A patent obtained following an application claiming the invention both of the process of manufacture of a pharmaceutical product and of the pharmaceutical product as such, but granted solely in relation to the process of manufacture, must not, by reason of the rules set out in Articles 27 and 70 of the TRIPs Agreement, be regarded, as from the date of entry into force of that agreement, as covering the invention of that pharmaceutical product”*.

On page 31, the Judgments added that:

“Even if, in fact, the Judgment dated 18 July 2013 does not specifically deal with that situation, the Rulings dated 30 January 2014 provide the same reply to cases that even go beyond the judged case, because they deal with patents applied for when the Reservation was in force and granted with product

and process claims many years later (patent ES 891, we recall, was only initially granted with process claims).”

As readers will have noted, the Judgment attributes to the Greek Court a question (*pending* patents granted after TRIPS came into force) that the Greek Court did not ask. The question asked by the latter mentioned *granted* patents only:

“(3) Under Articles 27 and 70 of the TRIPS Agreement, do patents covered by the reservation in Article 167(2) of the [EPC] which were *granted* before 7 February 1992 that is to say, *before the above agreement entered into force*, and concerned the invention of pharmaceutical products, but which, because of the aforementioned reservation, were granted solely to protect their production process, fall within the protection for all patents pursuant to the provisions of the TRIPS Agreement and, if so, what is the extent and content of that protection, that is to say, have the pharmaceutical products themselves also been protected since the above agreement entered into force, or does protection continue to apply to their production process only, or must a distinction be made based on the content of the application for grant of a patent, that is to say, as to whether, by describing the invention and the relevant claims, protection was sought at the outset for the product or the production process or both?”

C) The CJEU’s case law prevents it from altering the substance of the questions referred:

As the Judgment of 22 October 2014 correctly explains, the facts of the two cases decided by the two Rulings of 30 January 2014 had “notable differences” with respect to the case decided by the Judgment of 18 July 2013, because the former dealt with patent applications that were *pending* when TRIPS came into force. However, the crux of the matter is that, for reasons that only the Greek Court will know, it did not ask whether or not Article 70 of TRIPS obliged WTO Member States to permit the modification of patents that were *pending* when TRIPS came into force to claim the enhanced protection (i.e. the product) introduced by TRIPS. It asked the exact same question as in the *Daichi* case, which dealt with a patent *granted* in 1986, almost 10 years before TRIPS came into force.

And the CJEU highlighted as early as in 1982 that, regardless of the factual and legal background of the case before the national Court, the CJEU may not alter the substance of the questions referred by the national Court. For example, in § 14 of its Judgment of 20 March 1997 (Case C-352/95, *Phytheron International SA and Jean Bourdon SA*), the CJEU highlighted that:

“Finally, to alter the substance of questions referred for a preliminary ruling would be incompatible with the Court’s function under Article 177 [now 267] of the Treaty [...]”

Therefore, the “deduction” that the Judgment of 22 October 2014 makes on pages 27-31 in the sense that the CJEU would have answered a question (*pending* patents) different from the one (*granted* patents) submitted by the Greek Court is a rather risky deduction to make, as it amounts to attributing to the CJEU behaviour contrary to its own case law.

D) Suspension points [...] cannot provide guidance for national Courts on the scope of paragraph 7 of Article 70 of TRIPS, let alone constitute a solid basis to leave aside the interpretation agreed by the EU Commission, the WTO Secretariat and the Spanish Government in 1997:

If readers review the Judgment of 18 July 2013 and the two Rulings of 30 January 2014, the only reference they will find to paragraph 7 of Article 70 of TRIPS is the following suspension points:

“ ... ”

Construing these suspension points as the CJEU having affirmed that Article 70.7 of TRIPS (a provision not cited, let alone interpreted in any of these three CJEU’s decisions) did not oblige WTO Member States to permit the modification of patents that were pending when TRIPS came into force to claim the enhanced protection (i.e. the product) introduced by TRIPS, is certainly another long shot. For it would appear to be clear that a Decision explicitly omitting the citation and interpretation of a specific legal provision cannot provide any guidance for a national Court on how that legal provision should be interpreted, let alone constitute a solid basis to leave aside the interpretation agreed by the EU Commission, the WTO Secretariat and the Spanish Government in 1997.

At this point, it is worth recalling that, on 4 April 1997, the so-called “Inter-ministerial WTO Commission” of the Spanish Government, which is comprised of the top WTO experts of the Spanish Administration, after seeking the views of the EU Commission and the WTO Secretariat, agreed that Article 70.7 of TRIPS did oblige WTO Member States to permit the modification of patents that were pending when TRIPS came into force to claim the enhanced protection (i.e. the product) introduced by TRIPS. The Minutes of that meeting read as follows:

“Mr Cardedera subsequently provided information on the meeting held on 4 April, attended by the Director General for Foreign Trade, the Director General for Pharmacy and the Director of the Patent and Trademark Office, at which it was agreed that applications for process patents dating from before 7 October 1992 should, where requested, be processed in such a way that a product patent was granted, this being the form of protection afforded by Spanish law on that date. The terms of the TRIPS Agreement were thus complied with, since this is the most robust legal interpretation which is also favoured by both the European Commission and the Secretary General of the WTO, who have been informally consulted by Spain.

Thus, a doubt is resolved, which doubt was causing difficulties in the processing of files at the Spanish Patent and Trademark Office and the Department of Pharmacy itself, and we faithfully comply with the obligations imposed by the TRIPS Agreement, which allows us to require the same compliance by other Members.”

This interpretation has since been endorsed by both the Civil and the Administrative Chambers of the Spanish Supreme Court.

Mr. Renato Ruggiero, who at that time was the WTO Director General and who was visiting the Spanish Government, even attended the meeting on 4 April 1997. He was delighted to see that the Spanish Government was approving the right measures to comply with its obligations under TRIPS. To suggest that, due to the entry into force of the Lisbon Treaty on 1 December 2009 and the Daiichi Judgment, Spanish Courts should now undo the measures approved in 1997 to comply with Spain’s obligations under TRIPS, would certainly have a paradoxical result, i.e. Spain would instantly fail to fulfil its obligations under TRIPS, notwithstanding the Spanish Government and Spanish Courts’ firm efforts to respect them.

5. Conclusion:

At a time when everybody was expecting Barcelona Court of Appeal, one of the most experienced and respected Spanish Courts in patent matters, to cast more light on the TRIPS debate after the *imbroglio* caused by Daiichi and its saga, it has surprised the patent community with a decision that, for the reasons explained above, is clearly at odds with the function that the TFEU assigns to the CJEU in the

context of Article 267.

As always, the Supreme Court will have the last say.

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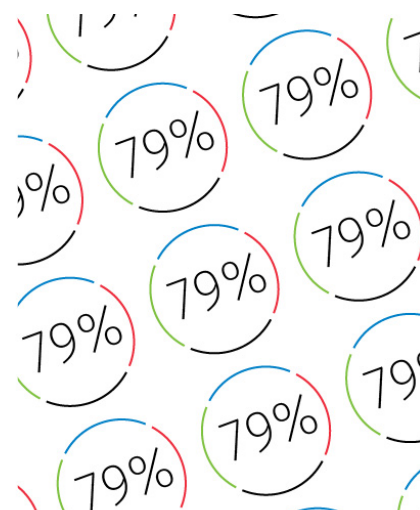
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