ES – COURT OF APPEALS OF BARCELONA – PATENT HOLDER V. SOLUCIONES BIOREGENERATIVAS S.L. – Contributory infringement

In this appeal decision dated 12 November 2020, the Barcelona Court of Appeals reversed a first instance judgment which had declared the existence of contributory patent infringement. Contrary to the first instance court, the Court of Appeals considered that since the concerned means for the implementation of the patented invention were products commonly found in trade, the requirement of inducing the person supplied to perform patent infringement was not met.

Background

As previously commented in this post accessible here, Barcelona Commercial Court no. 4, in a decision dated 9 September 2019, upheld the complaint filed by the patent holder of EP 1066838 (EP 383) against the company SOLUCIONES BIOREGENERATIVAS, S.L. (hereinafter referred to as "PROTEAL") through which the patent holder claimed that PROTEAL was contributory infringing claim 1 of patent EP 383 by marketing kits for obtaining PRFG (plasma rich in growth factors). However, in the appeal decision which will be analyzed in this post, the Barcelona Court of Appeals reached a different conclusion.

Claim 1 of patent EP 383 reads as follows:

> *1. A method for the preparation of a gel of plasma rich in growth factors (P.R.G.F.) from the blood of a patient, said blood having been extracted from the patient moments before the start of surgery and prior to the administration of anaesthesia, into tubes citrated to 10% with trisodium citrate, said method comprising:*
> *(a) centrifuging the tubes between 160-800 G for 6-8 minutes at room temperature to separate the blood into the following fractions: a fraction of red blood cells in the bottom part of the tube, a fraction of plasma rich in growth factors (P.R.G.F.) in the middle part of the tube, and a fraction of plasma poor in growth factors (P.P.G.F.) in the upper part of the tube;*
> *(b) extracting the plasma rich in growth factors (P.R.G.F.) fraction of the centrifuged product and transferring it to Eppendorf tubes or glass test tubes, adding 10% calcium chloride and waiting a period of time for the gel to form, where*
> *(c) the blood of the patient is not mixed with any other component of animal or human origin.*

As explained in the abovementioned post, PROTEAL marketed three type of kits (called Ortho.prass, Skin.prass and Dis.prass) which included several elements and substances for obtaining PRGF.

In particular, each of these kits comprised materials necessary for blood collection, materials necessary for plasma fractionation, sodium citrate to be used as an anticoagulant and calcium chloride to activate the plasma. All of that accompanied by a set of instructions for use detailing the steps to be followed to prepare PRGF. Additionally, together with the kits, PROTEAL also marketed centrifuges, whose centrifugation speed was predetermined in a range comprised within that set in claim 1 (1800 rpm for 8 minutes).

The first instance Court found that PROTEAL, by marketing the aforementioned kits and centrifuges, was contributory infringing claim 1 of patent EP 383. However, upon appeal, the decision was overturned.

Statute of limitations and unfair delay

First, and before entering into the merits of the case, the Court of Appeals went back on the issue of the statute of limitations, on which it agreed with the first instance court.

The patent holder had filed its claim 8 years after it first sent a cease and desist letter to PROTEAL. In view of this, PROTEAL claimed that the action brought by the plaintiff was time-barred (the deadline set forth in the Spanish Patents Act to bring patent infringement actions is of 5 years as from the moment the actions could have been brought). Alternatively, PROTEAL claimed that in any case the plaintiff would have incurred in unfair delay.

These allegations were rejected in first instance and confirmed by the Court of Appeals.

Regarding statute of limitations, the Court applied the Spanish Supreme Court case law according to which the limitation for bringing actions only starts running when infringement ceases. Therefore, in cases as the present one, in where the defendant had continued to market the allegedly infringing products (cases of “continuous infringement”), the actions arising from patent infringement cannot be considered to be time-barred.

Regarding unfair delay, the Court pointed out that for there to be disloyalty in bringing legal actions it is necessary to prove that the defendant had a reasonable expectation that the plaintiff would not exercise its actions. However, PROTEAL failed to provide any evidence thereof. PROTEAL just alleged the mere fact of time passing (8 years) since the first cease and desist letter before filing the claim. The Court considered that, without any further information or evidence being provided, the mere passing of time could not be considered as unfair delay.

Contributory infringement

The most interesting part of this appeal decision refers to contributory infringement, as it reversed the findings of first instance court on this issue.

In Spain, Article 60(1) of the Spanish Patent Act states:

> *"The patent also confers on its proprietor the right to prevent any third party not having his consent from supplying or offering to supply means for the implementation of the patented invention relating to an essential element thereof to persons not entitled to exploit it, where the third party knows or circumstances make it clear that such means are suitable for the implementation of the invention and are intended for it"*

Then Article 60(2):

> *"The provisions of the previous section shall not apply when the means referred to therein are products that are commonly found in trade, unless the third party induces the person supplied to perform acts prohibited by the previous article"*

Thus, according to the Court, for there to be contributory infringement, the following four requirements shall be met:

a) ***The infringer must provide the necessary means for the implementation of an essential element of the patent.***
b) ***The acquirer of these means must not be authorized to exploit the patent.***
c) ***The infringer must or should have been aware of the above circumstances.***
d) ***In the case of means that are commonly found in trade, the infringer must have induced the person supplied to perform direct patent infringement.***

The three first requirements were less of an issue for the Court of Appeals:

a) ***The infringer must provide the necessary means for the implementation of an essential element of the patent.***

Here the Court of Appeals agreed with the findings of the first instance court and considered that PROTEAL was indeed supplying means for implementing the plaintiff's patented method.

The issue centred on the question of whether, as alleged by PROTEAL, although the kits could be suitable for providing the means to implement the invention, these were or not intended to obtain a

different product from that obtained by the claimed method. In this sense, PROTEAL claimed the product obtained by the kits had two main differences with respect to the products obtained by the patented method: 1) PROTEAL's kits were aimed at obtaining a platelet-rich plasma (PRP), while the patented method is aimed at obtaining plasma rich in growth factors (PRGF) and 2) PROTEAL's kits were used to prepare a product in liquid form while the patent protected a product in gel form.

In answering this question, the Court of Appeals reached the same conclusion as the first instance court.

First, the Court followed the reasoning of the first instance court which had concluded that PRGF is a class of platelet-rich plasma (PRP). In arriving at this conclusion, the Court took into account a Spanish Medicines Agency's report which explained that the name of a product as PRP does not exclude that a PRGF is obtained, it would depend on the procedure followed. Consequently, from this point of view, the means to obtain a PRP also allow obtaining a PRGF.

Secondly, as for the alleged second difference, referring to feature (b) of claim 1, as said above PROTEAL maintained that the product obtained with its kits was a liquid plasma and not a plasma gel as the one protected by the patent.

However, it was not disputed that plasma activated with classical chloride can turn into a gel by waiting a period of time. This was not denied by PROTEAL. PROTEAL only denied that its kits gave precise instructions to users on how to obtain a plasma gel. But the Court considered that this was irrelevant. Regardless of whether the instructions or the advertising materials of the kits specify how to obtain plasma gel, it is a fact that plasma gel can be obtained by waiting a period of time, as explained by the patent itself (feature (b) of claim 1). Therefore, PROTEAL was providing the necessary means to put into practice this essential feature of the patent claim.

In conclusion, according to the Court, PROTEAL's kits comprised the essential elements for implementing the method for obtaining PRGF protected by claim 1 of patent EP 838.

b) The acquirer of these means must not be authorized to exploit the patent.

There was no discussion on the fact that health professionals to which products distributed by PROTEAL were addressed were not authorized to exploit the patented method.

c) The infringer must or should have been aware of the above circumstances.

The Court of Appeals considered that PROTEAL indeed knew that the supplied means were suitable for putting the invention into practice and were intended for it.

As said above, PROTEAL was perfectly aware that the plasma, once activated with calcium chloride, would gel after some time. Consequently, even if the instructions did not specifically point this, PROTEAL was perfectly aware that the kits could, if required for a certain treatment, obtain PRGF in gel form, thus reproducing the patented method. Moreover, even if this was not specifically indicated in the instructions for use, it was mentioned in the kits' advertising materials. Therefore, for the Court it was clear that PROTEAL knew that at least a part of the kit's users would use the product in gel form and thus implement the patented method.

d) The presence of means that are commonly found in trade and incitement to the person supplied to infringe.

The more controversial point for the Court was to ascertain whether we were "in presence of means that are currently commonly found in trade" and, if yes, whether the infringer had or not "induced the person supplied" to put the patented method into practice.

Here the Court of Appeals disagreed with the first instance court.

The first thing on which the Court of Appeals disagreed with the first instance court was on how the assessment of this two elements had been addressed. According to the Court of Appeals, it was first necessary to assess whether the concerned elements were means that are commonly found in trade and, secondly, whether or not the defendant had incited the infringement of the patent, and not the other way around, as the first instance court had done.

1) <u>Means commonly found in trade</u>

The Court pointed out that "products commonly found in trade" as defined in Article 60(2) of the Spanish Patent Act should be considered as "staple commercial products" in application of Article 26(2) of the Agreement on a Unified Patent Court, 2013/C 175/01.

Then the Court indicated that, according to Spanish doctrine, for these purposes, a staple product is a product that has at least one normal non-infringing use. In this respect, the Court of Appeals of Madrid, in a judgment dated 7 November 2011:

> *"In conclusion, when the means in question are commercially available and offer other applications apart from the one used to put the patented invention into practice, […] contributory infringement should be excluded, unless the third party induces the person supplied to commit prohibited acts".*

In the present case, the Court concluded that PROTEAL's kits were staple products, which included elements commonly found in trade, since by following their instructions for use, at least one non-infringing product could be obtained, i.e. a liquid plasma rich in growth factors (PRGF).

That said, the major point of issue for the Court was to decide whether or not PROTEAL had induced third parties to put the patented method into practice.

2) Incitement to infringe

In this decision, the Court of Appeals set a quite high standard for considering the existence of incitement to infringe.

The Court noted that "inciting" according to the dictionary means "strongly influencing a person to do a certain thing".

In the present case, although PROTEAL's kits included information in the instructions for use and advertising materials which allowed a third party to know that the kit could be used to reproduce the patented method (in particular, as explained above, kit's advertising materials indicated that plasma could transform from liquid into a gel by waiting a certain period of time), the Court noted that this information was already known by the third parties to which the kits were supplied.

Concretely, the Court considered that this information contained in the kits could not be considered an incitement in the sense that it could not influence the behaviour of third parties acquiring the kits, as long as such users to which the kits were supplied already knew or could easily deduce from the kit instructions that, by waiting a certain time, plasma could turn into a gel.

In other words, kit's users already knew that by activating platelet-rich plasma (PRP) with calcium chloride, as provided for in the kit instructions, the plasma begins a gelation or gelling process. Thus, for the Court, the fact that this kind of information was indicated in the advertising materials would not influence users to put the patented method into practice. PROTEAL was therefore not inducing kit's users to infringe.

Therefore, the Court of Appeals finally considered that no contributory infringement was being committed by PROTEAL.