

## **ES – ERASMUS MC & INVIVO v. VITRO et al.**

### **Court of Appeals of Barcelona, 8 April 2021, Appeal Docket No. 1969/2020**

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On 8 April 2021, the Court of Appeals of Barcelona rendered judgment on appeal in a complex case relating to nucleic acid amplification primers for PCR-based clonality studies, involving a number of issues regarding the assessment of inventive step, civil prejudiciality and compensation for damages.

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On 6 June 2017, the Erasmus University Medical Center (“Erasmus”), along with the company Invivoscribe Technologies, Inc. (“Invivoscribe”), filed legal actions for both direct and contributory patent infringement against Vitro S.A. (“Vitro”) and Master Diagnóstica S.L. (subsequently taken over by Vitro), in relation to certain kits, manufactured and marketed by these companies, for performing molecular studies linked to the detection of lymphomas, as well as to related reagents. The plaintiffs invoked their rights, respectively as owner and exclusive licensee, to the Spanish parts of European patents EP 2460889 (“EP’889”) and EP 2418287 (“EP’287”). These patents claim sets of nucleic acid amplification primers for PCR-based clonality studies (respectively, of BCL2-IGH rearrangements and of the TCR-beta gene) and relate to methods of analysis for the early diagnosis of lymphoid cancer. Legal proceedings already initiated were subsequently joined to other proceedings prompted against Erasmus by a third party (anonymized in the Judgment, hereinafter referred to as “X”) seeking the invalidation of EP’287 for lack of inventive step.

The Judgment of first instance (issued by Commercial Court no. 5 of Barcelona on 17 September 2019) rejected the invalidity claim against EP’287 and substantially admitted all claims for infringement -which had been undisputed- against Vitro, ordering an injunction against the infringing kits and awarding Erasmus and Invivoscribe compensation for damages, among other rulings.

Vitro and X appealed that decision, which was partially challenged by the plaintiffs as well. On 8 April 2021, the Court of Appeals of Barcelona handed down a Judgment answering all the questions raised on appeal.

Without going into the technical details of the case, whose high degree of complexity would exceed the purpose of this commentary, it is interesting to analyze how the Court of Appeals of Barcelona resolved the main legal issues submitted on the appeal of both parties.

**1. Determination of the objective technical problem.-** X, the claimant for nullity, had contested the first instance decision objecting to the Court's assessment concerning the inventive step of EP'287. Some of the objections raised on appeal by X essentially revolved around the determination of the objective technical problem in the first instance judgment, when applying the 'problem-solution approach'.

In the first instance judgment, the objective technical problem when starting from the closest prior-art document had been established as follows: *"the formulation of alternative primers to those of the previous state of the art, primers that make it possible to amplify and detect the rearrangement of the TCRB V $\beta$ -J $\beta$  using the PCR technique with adequate sensitivity"* (emphasis added).

X contended that the first instance court had disregarded that actually the EP'287 patent would not solve that objective technical problem. According to X, the court had wrongly assessed the evidence since detection sensitivity was not proven to actually improve with the EP'287 patent. The Court of Appeals thus noted that, in the appellant's view, the technical problem solved by the EP'287 patent would thus be improving detection sensitivity or, in other words, improving the rate of T lymphoma diagnoses.

However, contrary to the appellant's interpretation, the Court of Appeals found that the first instance court had not recognized or considered proven that the invention according to claim 1 of EP'287 intended to solve a sensitivity issue, in the sense of increasing the hit rate. The Court of Appeals noted that X had misinterpreted the judgment, which had merely referred to the fact that the patent would not improve sensitivity by echoing X's position on the objective technical problem, not as a finding of the court itself. Moreover, the Court of Appeals also considered it relevant that X had not objected to the description of the advantages of the claimed primers that Erasmus' expert had defended, even though none of those advantages consisted of improved detection sensitivity.

The Court of Appeals thus concluded that the improvement of the sensitivity or diagnosis rate of the new primers was not the main problem intended to be solved by the patent, for which reason it rejected X's ground of appeal.

**2. Influence of the declaration of nullity of the mother patent.-** For its part, the appellant Vitro contested the first instance judgment on grounds, among others, that the first instance proceedings should have been suspended because of civil prejudice. This argument -rejected in the first instance- was based on the fact that there were legal proceedings ongoing before the Courts in Granada for the invalidation of the "mother" patent, EP 1549764 ("EP'764"), of which EP'889 and EP'287 are divisional, whose lack of inventive step had already been declared in the first instance and on appeal (appeal in cassation pending). Hence, Vitro argued that the litigation concerning the divisional patents should have been suspended until the definitive conclusion of the former legal proceedings, in the

understanding that the final outcome concerning the validity of the “mother” patent EP’764 would have an impact on the proceedings relating to its divisional patents.

The Court of Appeals of Barcelona, agreeing with the assessment of the first instance judgment, found that there was no such prejudicial issue. It found that the Granada litigation related to a different patent, there being no objective identity between one procedure and the other. Accordingly, whether or not the “mother” patent was found to be valid, invalid or infringed, had no direct impact on the Barcelona proceedings. The Court also found that the statements made by Vitro before the first instance court to justify the necessary linkage were clearly insufficient, in a matter of such technical complexity, to establish any kind of interference with the “mother” patent’s declaration of invalidity. And, in any event, it recalled that EP’889 and EP’287, which had not been objected to on the grounds of added subject-matter, had been applied for and granted independently from EP’764, whose fate should therefore have no bearing on the disputed patents, in accordance with the case-law of the EPO Boards of Appeals.

It was consequently found that the “mother” patent’s status would have no impact on its divisional patents in justifying the suspension of the legal proceedings, for which Vitro’s appeal on these merits was rejected.

**3. Statute of limitations.-** The pre-existence of legal proceedings relating to the “mother” patent was also an argument for Vitro to contend that the infringement action based on EP’889 and EP’287 brought before the Barcelona courts was unfeasible. Vitro argued that these actions should have been raised by Erasums in the framework of and on the occasion of the Granada litigation, together with the infringement action of the “mother” patent EP’764 that it had lodged via counterclaim.

This argument, which had been rejected in the first instance, was discarded again in the appeal stage, for reasons similar to those that led the Court of Appeals to reject the existence of civil prejudiciality. Indeed, the Court of Appeals noted that Erasmus was under no legal obligation to enforce EP’889 and EP’287 before the Granada court, as those legal proceedings involved a different patent.

**4. Unfair delay.-** Also reiterating the arguments put forward in the first instance, Vitro contended that the actions for infringement of EP’889 and EP’287 had been filed with an unfair delay. In this vein, it argued that the registration before the Spanish Patent Office of the transfer and of the license of the patents EP’889 and EP’287 in favor of Erasmus and Invivoscribe, respectively, occurred later than in the case of the “mother” patent; given the absence of a simultaneous registration - Vitro defended - it could not expect to be sued on the basis of those patents. And, again, this alleged expectation also stemmed from the fact that the patents were not enforced in the Granada proceedings concerning the “mother” patent.

To resolve this ground of Vitro's appeal, the Court of Appeals resorted to the long-standing case-law of the Spanish Supreme Court regarding the doctrine of unfair delay, recalling that a contradiction between prior conduct and the subsequent claim must exist, and also that such a contradiction must objectively indicate a definitive attitude with respect to a given legal position, since the doctrine of unfair delay aims to protect the confidence held by a third party with regard to such previous conduct. In this sense, the mere inactivity, or the lapse of a long period until a complaint is filed, does not by itself objectively create a reasonable confidence that the right will not be enforced.

With the above principles in mind, the Court of Appeals did not observe any unfair delay on the plaintiffs' side either. It found that Erasmus' decision not to enforce EP'889 and EP'287 in the context of the Granada litigation, whose object was a different patent, did not make it possible for Vitro to objectively infer that Erasmus had thus demonstrated a willingness not to file suit for these patents. The fact that it took some time to register the assignment and the license could not be interpreted as Erasmus' willingness not to sue for the infringement of EP'889 and EP'287. These factors, together with the exceptional nature of the doctrine of unfair delay, led the Court of Appeals to reject this ground of Vitro's appeal as well.

**5. Damages.-** The first instance judgment had ordered the defendants to pay damages stemming from the patent infringement to be quantified in enforcement proceedings once the judgment became final, in accordance with the plaintiffs' claims. The damages thus awarded comprised three items: a) damages caused starting with the publication of the patents' granting in the EP Bulletin, according to the hypothetical royalty rule; b) compensation derived from provisional protection conferred onto the patent applications, where applicable, and c) coercive damages, where applicable. Vitro also appealed the order for damages based on several reasons.

5.1. Legal standing.- Vitro contended that the plaintiffs lacked the right to claim any damages in relation to any activities that took place before the patent assignment in favour of Erasmus, and the licence in favour of Invivoscribe, were recorded in the Spanish Patent Register, namely June/July 2016.

The Court of Appeals noted, however, that when the lawsuit for infringement was filed, in June 2017, both had their rights properly registered, so they were entitled to file suit and seek damages. The plaintiffs' legal standing to claim damages thus confirmed, the issue now became from what date such damages should be quantified.

5.2 Relevant period to claim damages.- In this respect, Vitro had challenged the earlier pronouncements in the first instance judgment establishing the starting date for quantifying damages: as from the publication of grant in the EP Bulletin, and also including any damages caused during the application stage by reason of provisional protection. It contended that, given that the plaintiffs' rights

to the patents were recorded in the Spanish Patent Register in 2016, damages could only be claimed and quantified as from that date and up to 5 years before the filing of the lawsuit, at most.

The Court of Appeals observed here that, actually, the plaintiffs had established as an initial date for determining damages, the dates of publication of the patents' granting -November and September 2013-, thus excluding provisional protection. Since this had not been claimed, it was wrongly awarded in the first instance judgment. On the other hand, November and September 2013 were covered by the time period of the 5 years prior to the filing of the lawsuit (June 2017), so estimating damages as from these dates was in accordance with Vitro's stance.

5.3 Proof of damages.- Vitro also argued that any suffering of damages by the plaintiffs had not been proven in the first instance, and so the appealed judgment lacked motivation regarding the awarding of damages.

In particular, the judgment established the following: *"Since any allegations and evidence on the causation of damages have been deferred to the enforcement phase, this resolution shall only establish any potential bases for its further development, admitting the existence of the infringement of the plaintiff's exclusive rights "* (emphasis added). Accordingly, the wording of the judgment suggests that any evidence on the causation of damages itself should be the subject-matter of later enforcement proceedings.

In this respect, the Court of Appeals recalled that, according to the Spanish Patent Act, quantification of damages may be deferred to later enforcement proceedings. However, the reality of damages themselves and evidence of same must be asserted in the main proceedings, during which the basis for future quantification should be clearly established.

In this vein, the Court found indeed that the appealed judgment offered very vague explanations about the reality of damages, especially considering the complexity of the issue as discussed in the first instance. However, despite these flaws in the appealed judgment, the Court of Appeals also found that the present case could admit the application of the "ex re ipsa" doctrine, according to which damages should be deemed inherent to patent infringement, in the understanding that the commercialization of the infringing kits should have necessarily had some impact on the marketplace. Therefore, despite the lack of precision in the first instance judgment, the Court considered the existence of damages inflicted on the plaintiffs duly proven.

5.4 Quantification of damages.- Lastly, the Court of Appeals observed that, while Vitro's appeal had focused on certain aspects regarding the plaintiffs' entitlement to damages and on the evidence of same, it had not raised specific arguments against what the Court of Appeals itself

considered to be *"ambiguous parameters set by the first instance judgment"* with respect to the quantification of damages.

The Court of Appeals noted that the judgment had left open significant questions regarding the basis for establishing specific compensation for damages, especially with regard to the hypothetical royalty, by referring to the plaintiffs' claims in general. These claims indicated that compensation should be calculated by considering an entry fee (undetermined), a minimum annual fee (undetermined), and a royalty on sales, estimated to be between 5-10% for Erasmus and between 10-25% for Invivoscribe.

In the Court's opinion, the ranges for the royalties were too wide. For this reason, it ruled that the royalty should be calculated based on the lowest parameter set forth in the complaint, i.e., 5%. Hence, even though the procedures for the quantification of damages were deferred to the enforcement proceedings, and even though the entry fee and the minimum annual fee had in fact not been specified, nonetheless the Court of Appeals considered it appropriate to set out a guideline to determine the royalty on sales in the declaratory proceedings, without prejudice to specific determination at the later enforcement proceedings.

Finally, it is worth mentioning that Erasmus and Invivoscribe challenged the first instance judgment, since it had declared that the quantification of awarded damages should be made in the enforcement stage, only after the judgment had become final, thus excluding the possibility of liquidating damages in a provisional enforcement. The Court of Appeals agreed with the plaintiffs that the law did not exclude a provisional liquidation of damages, thus entitling them to a ruling of damages in a provisional enforcement.

## **Court Decision**

All the above considerations led the Court of Appeals to fully dismiss the appeal filed by X with an order for costs, to partially admit Vitro's appeal, and to accept the challenge made by Erasmus and Invivoscribe. The Judgment could be appealed in cassation before the Supreme Court (whether it was filed or not is unknown as of the time of this writing).