FRENCH SUPREME COURT
Commercial Chamber
Public hearing of December 6, 2017
Case number 15-19726

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Dismissal

Presiding Judge Mrs. Mouillard

SCP Hémery and Thomas-Raquin, SCP Piwnica and Molinié, Attorneys

REPUBLIC OF FRANCE

IN THE NAME OF THE FRENCH PEOPLE

THE SUPREME COURT, COMMERCIAL CHAMBER, rendered the following decision:

Considering that according to the appealed decision (Paris Court of Appeals, January 30, 2015), Merck & Co. Inc., subsequently Merck Sharp & Dohme Corp., (hereinafter Merck) owns European patent EP 0 724 444 entitled "*Method of treating androgenic alopecia with 5-alpha reductase inhibitors*," filed on October 11, 1994, under the priority of two US patent applications of October 15, 1993, and March 17, 1994; that Teva Pharmaceutical Industries Ltd, an Israeli company, and its French subsidiary, Teva Santé, (hereinafter the Teva companies) summoned Merck based on article L. 614-12 of the Intellectual Property Code and articles 53 c), 54, 56 and 138 of the Munich Convention on the European Patent (EPC), claiming the cancellation of claims 1, 2 and 3 of the French part of this patent, for lack of novelty and insufficient disclosure as concerns claim 1, and lack of inventive step as concerns claims 2 and 3.

On the first ground:

Considering that Merck challenges the Court of Appeals' decision for ruling that the Teva companies' action is admissible, when, according to its argumentation, a first instance judgment that cancels an invention patent – even when it has been appealed – has force of *res judicata* from the moment it is handed down; that given the absolute effect attached to such a judgment, its force of *res judicata* is binding against all and, consequently, prevents a judge from ruling on a claim by a third party for the cancellation of the same patent, as long as the judgment has not been reversed; that, in the instant case, in a judgment of September 28, 2010, the Paris First Instance Court, on a claim of the Actavis Group companies and Alfred E. Tiefenbacher, pronounced the cancellation of the French part of European patent EP 0 724 444; that by admitting that – notwithstanding this decision that was subsequently confirmed by the Paris Court of Appeals – it was still admissible for Teva Santé and Teva Pharmaceutical Industries to bring a claim before it to challenge the validity of said patent, the Court of Appeals violated articles L. 613-27 of the Intellectual Property Code and 480 of the Civil Procedure Code.

Considering that, however, the Court of Appeals rightly stated that a decision cancelling a patent only has an absolute effect, as defined under article L. 613-27 of the Intellectual Property Code, once it has acquired force of *res judicata* and, having noted that the judgment rendered on September 28, 2010, cancelling patent EP 0 724 444 at the request of third-party companies, was under appeal, it inferred that it was admissible for

the Teva companies to seek the cancellation of said patent; that such ground is without merit;

And on the second ground:

Considering that Merck challenges the appealed decision for stating that claims 1, 2 and 3 of the French part of its patent EP 0 724 444 are null and void for insufficient disclosure, whereas, according to its argumentation:

1°/ an invention is sufficiently disclosed when the skilled person is able to implement the invention upon reading the disclosure and using his normal, theoretical and practical professional knowledge; in the instant case, claim 1 of European patent EP 0 724 444 relates to "*the use of finasteride for the preparation of a medicament for oral administration useful for the treatment of androgenic alopecia in a person and wherein the dosage amount is about 0.05 to 1.0 mg*;" in considering that the invention covered by said claim and by the dependent claims 2 and 3 was insufficiently disclosed, without finding that the skilled person, upon reading the patent and with his professional knowledge, would not have been able to prepare such a medicament for oral administration with a finasteride dosage between 0.05 and 1.0 mg, the Court of Appeals violated articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

2°/ the assessment of the sufficiency of a patent's disclosure cannot be confused with that of its novelty or inventive step; in order to assess whether an invention claiming a specific dosage is sufficiently disclosed, one need only seek whether the invention is disclosed in a sufficiently clear and complete manner for a skilled person to be able to implement it, and not seek whether the patent discloses a "*specific technical teaching*" by comparison with the prior art; in the instant case, it appears from the very terms of Claim 1 of the patent that the only therapeutic effect claimed for the use of a dosage of finasteride between 0.05 and 1.0 mg is its usefulness for the treatment of androgenic alopecia; in stating, to consider that the invention suffers from insufficient disclosure, that the disclosure does not allow "*a comparison of the effects of the dosage claimed against the state of the art with a larger dosage in the area of 5.0 mg*," that it does not disclose the "*specific pharmacological properties [of the new therapeutic application claimed] as compared with the state of the art*" and thus discloses no "*specific technical teaching*" – when all it was called upon to do was determine whether the information provided in the disclosure was likely to make the therapeutic efficacy of the dosage claimed plausible for the treatment of androgenic alopecia – the Court of Appeals violated articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

3°/ courts are not allowed to distort the documents of the case; in the instant case, it is stated, at the end of the disclosure relative to example 4, that "*by using the methodology disclosed above, it can be shown that the administration of finasteride, with daily doses per patient of, for example, 1 mg/day or 0.2 mg/day, is useful for the treatment of androgenic alopecia, and promotes hair growth in patients suffering from this condition*;" by noting that example 4 does not disclose the technical effect resulting from the reduction of the dose claimed, the Court of Appeals distorted European patent EP 0 724 444 and violated the above-mentioned principle;

4°/ for a claim relating to a therapeutic use to be considered as supported by the disclosure, it is not necessary to provide clinical proof of a therapeutic effect; in the instant case, the Court of Appeals noted that example 4 disclosed a 12-month operating protocol to detect hair growth using a photographic camera, but that it did not disclose the experimentation or the technical effect resulting from the reduction of the claimed dosage and that it could not constitute a test report; in thus demanding clinical evidence of the therapeutic effect produced by the claimed dosage, even though it had just reiterated the fact that it was not necessary to provide clinical evidence of the therapeutic effect of the invention, the Court of Appeals failed to draw the

legal consequences of its own findings, in violation of articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

5°/ for a claim relating to a therapeutic use to be considered as supported by the disclosure, it is not necessary to provide clinical proof of a therapeutic effect; the invention is sufficiently disclosed if the information provided in the disclosure is likely to make the therapeutic application claimed plausible; in the instant case, the Court of Appeals noted that example 4 disclosed a 12-month operating protocol to detect hair growth using a photographic camera, but that it did not disclose the experimentation or the technical effect resulting from the reduction of the dose claimed and that it could not constitute a test report; by ruling in this way, without seeking to determine – as it was invited to do – whether the operating method disclosed in said example 4 did not provide the skilled person with a procedure allowing him to verify the effects of the dosage claimed on the treatment of androgenic alopecia and whether this did not thus make such effects plausible, the Court of Appeals failed to ground its decision on any legal basis under articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

6°/ for a claim relating to a therapeutic use to be considered as supported by the disclosure, it is not necessary to provide clinical proof of a therapeutic effect; in noting that example 5 does not specify the details of the experimentation or the protocol applied and that it only reports a substantial decrease in the DHT content in the scalp and not hair regrowth or the end of hair loss, the Court of Appeals once again required clinical evidence of the therapeutic effect produced by the dosage claimed; by ruling in this way, after having initially reminded that it was not necessary to provide clinical proof of a therapeutic effect of the invention, the Court of Appeals failed to draw the legal consequences of its own findings, in violation of articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

7°/ for a claim relating to a therapeutic use to be considered as supported by the disclosure, it is not necessary to provide clinical proof of a therapeutic effect; the invention is sufficiently disclosed when it is evidenced that the compound claimed has a direct effect on a metabolic mechanism involved specifically in the disease to be treated, said mechanism being either known in the prior art, or proven in the patent itself, so that the therapeutic application claimed appears plausible; in noting that example 5 does not specify the details of the experimentation or the protocol applied and that it only reports a substantial decrease in the DHT content in the scalp and not hair regrowth or the end of hair loss, without explaining – as it was invited to do – the fact that the patent disclosure also stated that DHT is the main mediator of androgen activity and that the decrease in the DHT content in the target tissue of interest avoids or diminishes the symptoms of hyper-androgen stimulation in said tissue, including androgenic alopecia, and without seeking to determine whether the study mentioned in said example 5 was not likely to show that the dosage claimed has a direct effect on the metabolic mechanism involved specifically in androgenic alopecia, namely DHT, the Court of Appeals failed to ground its decision on any legal basis under articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

8°/ the sufficiency of the disclosure must be assessed from the point of view of the skilled person at the priority date; based on the contents of the patient information leaflet for the product "Propecia" sold by Merck for the treatment of androgenic alopecia, to consider that example 5 is "not entirely reliable," without finding that the skilled person would have been aware of said patient information leaflet at the priority date claimed by the patent, the Court of Appeals ruled based on irrelevant grounds, in violation of articles L. 614-12 of the Intellectual Property Code and 138 of the Munich Convention on the European patent;

9°/ the experiment disclosed in example 5 of European patent EP 0 724 444 shows only a substantial decrease in the DHT content in the scalp tissue of the participants after six weeks of treatment and not hair regrowth within this timeframe; because it merely noted, to assert that the test mentioned in example 5 is "not entirely reliable," that the summary of characteristics for "Propecia" mentions a hair regrowth efficacy

that appears only after a period of three to six months, namely at least twelve weeks, without explaining – as it was invited to do – the fact that hair regrowth necessarily takes place after the decrease in the DHT content, the Court of Appeals' decision is flawed for lack of grounds, in violation of article 455 of the Civil Procedure Code;

However, considering that, first, when a claim relates to a further medical use of a substance or composition, the achievement of said therapeutic effect is a functional technical feature of the claim, so that even though it is not necessary to provide clinical evidence of said therapeutic effect to satisfy the requirement of sufficiency of disclosure, the patent application must nevertheless directly and unambiguously reflect the claimed therapeutic application, so that the skilled person can understand, based on commonly accepted models, that the results reflect said therapeutic application; the decision notes, first, that as concerns claim 1, which protects the use of finasteride to prepare a medicinal product for the treatment of androgen alopecia in men or women, administered by oral route according to a certain dosage, the disclosure does not indicate the advantage or technical effect resulting from this type of oral administration, nor does it contain any element showing the potential efficacy of any dosage of finasteride, or any information on the new effect of the dosage claimed and the specific properties of this new therapeutic application, the dosage between 0.05 and 1.0 mg being indifferent, unlike the frequency of administration and the patient's body mass; the decision then notes that the patent disclosure mentions only the "*surprising and unexpected*" discovery of this new therapeutic application, without disclosing the specific pharmacological properties thereof as compared with the state of the art, which are only the result of an arbitrary choice; from such findings, the Court of Appeals was able to infer that the patent application did not directly and unambiguously reflect the claimed therapeutic use, and that the skilled person, being unaware of any specific technical teaching, would be unable to reproduce the invention and would be forced to initiate a research program himself, so that claim 1 suffers from insufficient disclosure, as does claim 2, which is a dependent use of claim 1 in which the dosage is 1.0 mg, and also claim 3, dependent on claims 1 and 2, in which the treatment is that of male pattern baldness;

And considering that, second, concerning the examples mentioned in the patent disclosure, the Court of Appeals, based on its own reasoning and on reasoning adopted from the first instance decision – after having dismissed examples 1 and 2, which pertain to the preparation of finasteride, a manufacturing process already known for several years, and example 3, which does not cover androgen alopecia – first noted that example 4 discloses a photographic operating method to detect hair growth by counting hairs over a 12-month period, and held that, as this example provides no information on the conditions of a possible test and does not disclose the experimentation or the technical effect resulting from the reduction of the dose claimed in relation to the dosages of the prior art, said example appears to be a measurement method and cannot be considered as a test report; it then noted that example 5 provides no details as to the experimentation or the protocol applied during the administration of finasteride during six weeks, the result of which showed a substantial decrease in the DHT content but did not evidence hair regrowth or the end of hair loss, and held that, in the absence of any criteria for comparison, when the decrease in the DHT content in the scalp caused by the administration of finasteride was already known, said example does not allow a comparison between the effects of the dosage claimed and a larger dosage, in the area of 5 mg, included in the state of the art; it was therefore without distorting the patent or requiring clinical evidence of the therapeutic effect of the new dosage, that the Court of Appeals – which did not have to carry out the irrelevant research raised in the fifth and seventh branches, and overlooking the superabundant argument criticized in the last two branches – considered that, as such examples do not directly and unambiguously reflect the claimed therapeutic use, they could not remedy the insufficiency of disclosure thereof, otherwise noted;

Therefore, the argumentation is without merit in all its branches;

ON SUCH GROUNDS:

DISMISSES the appeal;

Orders Merck Sharp & Dohme Corp to pay the court fees;

Considering article 700 of the Civil Procedure Code, orders it to pay Teva Pharmaceutical Industries Ltd and Teva Santé a global amount of € 3,000 and dismisses its claim;

Thus made and ruled by the Supreme Court, Commercial, Financial and Economic Chamber, and handed down by the Presiding Judge at the public hearing held on December 6, 2017.