

Judgment of the Court of Appeal of Lisbon

Procedure: 7935 / 08-7

Document Number: RL201001267935 / 08-7

judgment of the date: 26-01-2010

DECISION FULL TEXT:

Agree on the Lisbon

Appellant (s): M. and other

Appealed: T, SA

Request: Change the answers given to arts. 1, 8, 9, 15, 16 and 17 of the base and withdrawal of instructory contested sentence.

I. T, SA., Brought a declaratory action in the ordinary way against US commercial company M under which asked to be declared void the Portuguese patent No, requested by R. in Portugal, 7 June 1990 and issued on 02/24/97 and in the alternative, in case your main claim is not proceed, they were declared zero to claims 1st to 4th of the same patent.

He claimed, in summary, to commercialize a medicinal product which is mainly active salt monosodium trihydrate of alendronate, for the treatment of non-vertebral bone fractures and prevention of osteoporosis in postmenopausal women. On June 7, 1990 to R. required protection in Portugal, as a process patent the patent which was declared invalid in the context of the present case, The required by the PTO .. The invitation, in November 1996, claims R. were changed, passing, Thus, the claims include product, from the patent to be granted on 02.24.97. However, changes to claims were not published, which makes nullable patent. Claimed also the A. that the law applicable to the case is the law in force at the date of the patent application (Industrial Property Code 1940), under which no could be subject to industrial patent pharmaceutical compositions intended for the man, but only the processes to obtain them. On the other hand, still held the A. that the patent at issue claims a new substance which was not described or characterized in that the same and no new substance reveals activity inventive, since alendronic acid salts were already known, in particular acid monosodium, having its action have been published and patented as a useful drug for bone disorders, in particular by Patent Institute ... in which it was found alendronate - Alendronic acid and salts thereof, referring to the fact that the salt monosodium alendronic acid having three water molecules associated adds nothing to their action as pharmaceutical product. We conclude therefore that A. sustaining the addition of said three water molecules it is 2/16

a discovery and not an invention, so its lack of novelty and inventive activity to determine invalidity of the patent owned by R ..

Regularly cited, R. did not dispute.

Despite the silence of R., the MD societies, Lda., MS, Ltd., C, came deduct intervention incident spontaneous principal and present its defense, under which pugnaram for the dismissal of the action and for acquittal of R. and stakeholders of the net application.

Held preliminary hearing sanitizer order was made, having been selected facts and that the integral ground instructory basis.

After completion of the discussion and hearing, judgment was rendered noting the origin of the action, declaring it null Portuguese patent No requested by R., Mc., the INPI in 6.7.90 and granted by order of that institute dated 24/02/1997 and published on 20/05/97.

It is against this decision that the appellant objected, arguing its appeal, in conclusion:

[1] 1.a) were incorrectly judged that the points listed under paragraphs. Paragraphs 1, 8, 9, 16 and 17 of decision given on the facts (see paragraphs 1 to 5 of the claim.);

2.a) Indeed, this point stated under no. 1 ° should be given as proved, or, when it does not understand, shall cancel the resolution given in the 1st instance, in this regard, in accordance with Art. 712-4, CPC (cf. No claim 2.);

. 3rd) whether the point stated in paragraph 8 should be taken as not proven (see paragraph 3 of the claim.);

4.a) For the statement that point under no. 9 °, must be annulled pronouncement I instance, in this regard, in accordance with the requirement laid down in art. 712-4, CPC (cf. paragraph 4 of the claim.);

. 5.a) The fact that the items listed in paragraphs 16 and 17 must be considered - if not proven (see the claim No. 5);.

6.a) refined and corrected in molds and exposed narrow as possible, the facts, it appears, from any event, the judgment of the 1st instance upheld the action only by having understood that there tampering and failing publication or public announcement thereof in respect of the EN 94 claims 306 that holds the first? Defendant, Appellant here, - which would represent a substantial procedural violation, generating total invalidity of the same patent;

7.a) And, in doing so, the M ° "Judge defendant felt empowered and legitimized not know the remaining issues raised in the dispute, by virtue of the

8th) But the legal prohibition of change of essential and characteristic elements of the patent, model, design or registration due to estatuição art. 26-1, CPI 1995 refers only to industrial property rights already granted, and not to their requests;

9.a) In the present kind, the changes demanded in the claims of the invention introduced occurred

during the phase of the pending request and not discuss the claims EN 94 306 after granting this;

10th) Moreover, there is, in the known laws, any 'principle of stability ', which prohibits, as a rule, inclusion of changes to patent applications, including the claims, at the time of its assessment and your decision;

11th) On the other hand, the TRIPS Agreement not only allows you to change the order, such as determining the content of this change (Modified claims, in order to achieve product protection, not only of the process initially claimed: - art. 70, paragraphs 7 and 8).;

12th) The standard of art. -7 70 of this TRIPS is likely to be directly applied to solve cases concrete in the Portuguese legal order, has put on self-executing nature;

13.a) addition of Claims EN 94306 are supported on this description the patent, which provides the bases for the invocation of the invention as relating to a new product (in addition to the process corresponding preparation);

14th) So it was not introduced new matter, during the formal addition to the primitive claims, containing up to Claims added under description;

15th) Since the entry into force of Decree Law 27/84, of 18 January, ace claims, the Portuguese legal system, are not published, the same holds for the description and to the drawings;

16th) What is published is merely a summary of invention (Art. 58, par. D) CPI 1995), which produces no legal and material effects, and only plays a disclosure function of technological information;

17th) The required disclosure is made exclusively through 'notice', with 'transcription of the abstract "- not It includes the claims - which had already been made in the "Bulletin of Industrial Property" (Article 62-1 and 4, CPI 1995);

18th) and 'short' is the summary of the invention, and not the summary of the patent, including the claims, i.e., what is protected by the patent; as to the latter, nothing is published, the face of national law;

19.a) In addition to the above, it is certain that the invalidity of a patent foundations are subject to the principle of legality and typicality;

20th) The procedure for obtaining a patent is an administrative procedure;

21st) According to the rules that dominate the Administrative Law, failure to comply with a formality - the publication of claims - that the law does not require many years, can not serve as a ground of nullity of the right, constitutionally enshrined, given to the inventor (Article 42-2, CRP.);

22nd) the safeguarding of the legitimate interests of third parties is expressly provided for in the recommendation contained in art. 70 ° -4 TRIPS Agreement and has host of art. 104 of our CPI 2003, which also applies to patents awarded under the CPI in 1995 or previous legislation;

23rd) A judicial decision under censorship violated by mistake of interpreting and applying the provisions of art. 42- 2 of the Portuguese Constitution, art. 70 ° -7 of the TRIPS Agreement, the arts. 26-1, 58- d), and 62-1 and 4 Industrial Property Code of 1995 and art. 104 of the Industrial Property Code 2003.

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The appealed counter-claimed, fighting for confirmation of the judgment.

II.1. Given the content of the conclusions of the appellant's claims that, pursuant to arts. 684 paragraph 3 and 690.º1 the CPC, define the subject-matters to be decided are whether: (i) given the evidence produced at the hearing should not be changed or the decision on Articles 1, 8, 9, 15, 16 and 17 of the base and if instructory so, the contested decision be revoked; (li) from a legal point of view, more fulfilled, in that the law issues do not become damaged by the solution given to questions of fact, if the insert is admissible changes to patent applications, including the claims at the time of its assessment and its decision; at En 94 306 of the claims are within the scope of the original patent specification, which provides the basis necessary for the invocation of the invention as focusing on a new product (in addition to the process corresponding preparation); the publication of the invention is confined to a mere glance, without any effect legal and material but only plays a disclosure function of technological information; not to publication of claims can not serve as a legal ground of nullity.

II.1.2 In the first instance based data as were the following facts:

1- A. is a Portuguese commercial company engaged in the trade of products and specialties pharmaceutical.

2- sells products that are mostly drug whose active substance is no longer patent.

3- Alendronic acid is the generic name used in pharmacy, the compound whose chemical name is acid (4-amino-1-hydroxybutylidene) bisphosphonic.

4- A of medicinal products intended A. market is a compound having as a principle active monosodium trihydrate salt of alendronic acid - known as alendronate.

5- alendronate is recognized in the medical and pharmaceutical community as particularly intended for the treatment of non-vertebral bone fractures and prevent osteoporosis in postmenopausal women.

6 In a study published in 1978 in the Bulletin of the USSR Academy of Sciences, No. 27, 374-377 and signed by K, News was given first of the preparation of alendronic acid by reacting the Y-aminobutyric acid, phosphorous acid and phosphorous chloride in the absence of solvent.

7. On 16/02/1983, the German company was granted European Patent EP H that does not designate Portugal dated

reporting the priority 04.28.1980 claims in which the process of preparation of alendronic acid per phosphorus trichloride action or phosphorus pentachloride in conjunction with phosphoric acid on acid 4-aminobutyric acid with or without solvent and after acid hydrolysis (non-oxidizing strong acid, including, for example, p-toluensulfonic acid).

8 - With the date of deposit reported to April 15, 1982, it was published in Italy to patent - "Bifosfonati farmacologicamente attivi, procedura per la preparazione e relative composizioni Farmaceutiche "that holds the Italian company Instituto, SPA

9 - This patent claims pharmaceutical compositions containing 4- amino-1-hydroxy-butane-1, 1-bisphosphonic acid 5/16

or more briefly, alendronic acid, including their salts with alkali metals, organic bases and bases combined amino acids, as well as a process for obtaining it.

10 - Sodium is an alkali metal, and are thus included in the claimed subject matter any acid sodium salt Alendronic such as the monosodium salt.

11 - In that patent is described and claimed that the alendronic acid and its salts have therapeutic efficacy may be used as active substances in medicaments for the treatment of bone diseases, more efficacy and lower incidence of side effects than other known substances to date of deposit.

12 - The IT ... presents results of clinical tests for primary hyperparathyroidism, Paget's disease, hypercalcemia neoplastic and neoplastic osteolysis as well as toxicological studies data.

13 - The IT also claims a process of preparing target biosfonic acids, among which stands alendronic acid or pharmaceutically acceptable salts thereof.

14 - O claimed process is characterized by:

- if you reacting an amino acid or a precursor thereof with phosphorous acid and phosphorus trichloride in an inert solvent,
- if hydrolyzing the reaction product.

15 - This patent was also granted in the United States to that company Instituto ... in 04 November 1986, which has no (As pgs document. 111 to 114 of the file, the contents of which here occurs by reproduced in full).

16 - US Patent consists of records of the regulatory authority of American medicine, Food and Drug Administration - FDA as a basis for the patent registration F ... medicine. In the USA.

17 - And in the international symposium of drug analysis organized by the Department of Science Pharmaceutical University of Antwerp, Belgium and the Belgian Association of Pharmaceutical Sciences that had held from 10th to 16th May 1989 we presented a paper titled "The determination of 4-amino-1, 1-hydroxybutane-1, 1-diphosphonic acid monosodium salt trihydrate form a pharmaceutical HPLC.

18 - AM owns in Portugal PT, required on 06/07/1990, entitled was "process for preparing the 4-amino-1-hydroxybutylidene acid-1, 1-bisphosphonic acid or salts thereof "(as fls.115 document and the following case, the content of which is given incorporated by this reference).

19 - In this application was claimed the right of priority under Art. 4 of the Paris Convention of 1883, in relation to patent application United States of America ... No .. of 09/06/1989, whose patent was the later assigned the number US

20 - The object of this patent description of the invention relates to an improved process (sic) for the preparation alendronic acid and its salts.

21 - Indicates the technical field to which the invention pertains - preparation of 4-amino-1-hydroxybutylidene-1, And 1-bisfosfónico-.

22 - refers expressly and literally that according to the prior art that is reflected in the US Patent and

European Patent No. designates not Portugal, "to prepare 4-amino-1-hydroxybutylidene-1 acid, 1-bisphosphonic acid by reacting an aminocarboxylic acid with a phosphonating reactant and then hydrolyzing the reaction mixture by addition of concentrated hydrochloric acid with heating. result 6/16

problems of this reaction because it does not remain homogeneous and local solidification occurs. This solidification is Because of variable income (...). Moreover, to make the sodium balance art processes using above, requires the isolation of 4-amino-1-hydroxybutylidene-1 acid, 1-bisphosphonic acid and an additional step for convert the monosodium salt. "

23 - also refers literally to the invention object of the patent "solves these problems by allowing the reaction remain fluid and homogeneous making it possible commercial manufacture, reducing the number of process steps and providing a large improvement in isolated yield of 45-50% to 85-90% (sic).

24 - In this patent application the following claims were made:

1st - Procedure for preparation of 5-amino-1-hydroxybutylidene-1,1-bisphosphonic acid or its salts characterized comprising:

- a) reacting 4-aminobutyric acid with a mixture of phosphorous acid and PC13 in the presence of acid methanesulfonic, and
- b) recovering said 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid or salts thereof.

2nd - Process according to CLAIM 1, characterized in that said reaction is conducted at a temperature from 45 C to 125.°C.

3rd - Process according to CLAIM 2, characterized in that said reaction is conducted at a temperature of about 65.°C.

4th - Process according to claim 3, characterized in that the recovered monosodium salt trihydrate

4-amino-1-hydroxybutylidene-1, 1-bisphosphonic.

25 - The National Institute of Industrial Property, by letter of 11/15/96, on the application of patent No.

..... R. ordered to promote the replacement of the claims made by others in accordance with the European patent. "

26 - thus changed R. claims of that patent the following:

1st - compound characterized in that the crystalline monosodium salt trihydrate acid

4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid.

2nd - A compound according to claim 1, characterized by being in the form of a free flowing powder.

3rd - A compound according to claim 1 or claim 2, characterized by being used in preparation of a pharmaceutical composition.

4th - A pharmaceutical composition comprising a compound according to claim 1 or to claim 2.

5th - Process for the preparation of a compound according to reivindicação1 or 2, characterized in that understand:

a) reacting 4-aminobutyric acid with a mixture of phosphorous acid and PC13 in the presence of acid methanesulfonic, at a temperature less than 85 C.

b) treating with water;

c) bringing the pH to 4.3 with sodium hydroxide solution at a temperature of -20 25.°C;

d) cooling and 0-5.° C

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e) collecting the desired compound by filtration, washing with water and 95% ethanol and air drying.

6th - Process according to claim 5, wherein step (a) is performed in the absence of a diluent.

7th - Process according to claim 5 or claim 6, wherein step (a) is performed

to about 45 C and step (e) is carried out at about 40 C.

8th - Process according to any one of claims 5 to 9, characterized by using 1.5 mol H3PO4

PC13 and 2.4 mol per mol of 4-aminobutyric acid.

9th - Process according to any one of claims 5 to 8, characterized in that in step c) employing Sodium hydroxide solution 50%.

10th - Process according to any one of claims 5 to 9, characterized in that the solution obtained in step b) C 95-100.° to be aged before the initiation of step c).

27 - and the PTO by order of 24 February 1997 granted patents containing such that CLAIMS protect the product or compound.

28 - These changes to patent claims have not been any published or public notice.

29 - alendronic acid salts have been known and in particular the monosodium salt.

30 - Its action as useful drugs for bone disease had been discovered, published and patented.

31 - The aforementioned patent of the Institute is part of the registration information of the F medicine in the US, and this patent does not disclose any hydrated forms.

32 - Already after the concession of PT It has been verified the existence of an error in claim 1, the omission of the term crystalline, having been requested, granted and published change.

33 - In contract 1 March 1993 (and partially modified on 26 October 1995), M.

granted to MS, an "exclusive sub-license agreement with the licensed patents within the territory to do, have made, packaging, use and sell the product with the right to grant sublicenses to affiliates, and the the term "product" means "the prescribed form for administration to human therapy containing compound as an active ingredient alone or together with other active ingredients "and the term" Compound "

It meant the chemical 4-amino-1-hidrobutilideno acid -1, 1-bisphosphonic acid, also known as alendronate (paragraph 1.1).

34 - On 21 August 1987, the MS has changed its name to MSD.

35 - By contract signed on September 1, 1997 (and partially modified on 29 December 1999), the MSD., As the holder of the rights, the exposed mold, you had arising from the M, granted C

an exclusive license under the patents licensed within the territory to make, have made, use and sell the product with the right to grant licenses to branches.

36 - By contract signed on September 1, 1997 (and partially modified on 29 December 1999), the C granted MS (Ltd.) an "exclusive sub-license agreement with the licensed patents and know-how in the territory to make, have made, use and dispose of the product with the right to grant sub-licenses to branches. "

37 - Finally, by agreement in May 2001, MS. granted to MS, Lda. a nonexclusive for PT "to import and sell products covered" by it.

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38 - has been granted MSD Ltd, by Infarmed by order of 12/06/1996, authorization to place.

F ... market medicament containing, as active ingredient, alendronate sodium, as document pgs. 471-472 the file whose content is given here for playing.

39 - was awarded to A. at Infarmed by order of 03.02.2000, authorization for placing on the market Osteodronato called medicament containing, as active ingredient, alendronate, according to the document on pages. 474 and following of the file whose content is given here for playing.

40 - The A. has not asked nor received consent or license M., nor any dealer of their

rights, including the stakeholders to prepare and market in Portugal the "Alendronate".

41 - Not acquired them that active substance.

42 - is described in the text of a substance EN 94 306 - monosodium salt of alendronic acid in its trihydrate form.

43 - The final phase of the process reivindicadao EN 94 306 involves the use of water and tenal and since the content of ethanol is very low (<0.01%), the loss on drying is due to the total water in the product.

44 - The trihydrate of monosodium salt of 4-amino-1-hydroxybutylidene-1 acid, 1-bisphosphonic acid (alendronate) has such as the name indicates, three water molecules per acid monosodium salt molecule 4-amino-1-hydroxybutylidene-1, 1-bisphosphonic acid.

45 - This is a water content, by KF at least 16.6%.

46 - And the weight loss by drying is 16.7%.

47 - The analytical techniques such as X-ray diffraction spectrum, nuclear magnetic resonance and calorimetric Differential formed part of the prior art at the filing date of the patent.

48 - The fact that the monosodium salt of alendronic acid molecule has three water molecules associated nothing adds to its therapeutic action.

49 - The process claimed in EN:

- using an amino (4-aminobutyric acid)

- uses phosphorous acid

- uses phosphorous trichloride

- uses no solvent, but says on page 3 that "... the reaction can be conducted if desired in the presence of a ... inert organic diluent "

- carries out hydrolysis of the reaction product from the reaction product.

50 - That is, also uses an amino acid; also uses phosphorous acid; also uses phosphorus trichloride; also causes hydrolysis of the obtained product; can also be carried out in the presence of a solvent (or diluent) which Process characteristics are described and claimed in IT 20781.

51 - Through the process claimed by the en 94 306 is not isolated and the acid salt is obtained directly;

52 - The active principle and pharmaceutically acceptable industrial application of the claimed product in PT 94 306 are the same for one of the products covered by the IT 20,781.

53 - Notwithstanding, only the trihidrata form in which the active ingredient arises.

54 - A reading of the patent H and as to the aminobifosfónicos acid production process it is found that 9/16

method of adding a non-oxidizing strong acid, such as hydrochloric acid (preferred), with heating to hydrolyze the formed phosphorous intermediates and yield the final product is more problematic than methods correspondents in PT and it

55 - This is due to the bisphosphonation reaction mixture remains homogeneous and no solidification occurs place the determining variable yields, due to the formation of "hot spots" during the exothermic reaction with the acid.

56 - This results in a poor distribution of heat which contributes to the formation of by-products, yields low and the possibility of thermal accident, not to mention the cost of own acid-proof reactors strong.

57 - The Institute It is part of the group of companies of M. since 1997.

58 - The problem solved in the patents GB U.S. Patent and EP was the formation of mixtures and inhomogeneous glazing and also the use of hydrochloric acid.

59 - And it could by using, as the reaction solvent, methanesulfonic acid allows the reaction medium remain fluid and homogeneous and that obtain high yields of alendronic acid.

60 - From the alendronate, M. salt obtained by addition of water and sodium hydroxide to the mixture, which contains alendronic acid and the desired product - the crystalline trihydrate of monosodium salt of alendronic acid - crystallizes and is filtered off, isolating the acid making unnecessary.

61 - The advantage of the process consists of the M. directly obtaining the crystalline acid monosodium salt trihydrate Alendronic, without isolating the alendronic acid claimed in claim 5 in PT;

62 - Monosodium crystalline trihydrate of alendronate shows physico-chemical facility handling and stability.

63 - Example 2 PT refers to a characterization of test raw material in which the content is determined total water, or hydration molecules ie humidity.

64 - And, in this example 2 is that the result of a determination by the Karl-Fischer method - a method to dosing the water - 16.6% - which confirms the expected theoretical value of 16.61 (5) for the product% questioned.

65 - The two mentioned determinations do not indicate whether it is a salt with moisture or if it is a hydrate.

66 - Check that it is a trihydrate was made by X-ray crystallography

67 - All the water derived from water of crystallization molecules and the substance has absorbed water produced when in a significant quantity is formulated.

68 - crystallinity and absence of moisture such that confer to the new product flow properties important in the area of pharmaceutical formulation.

II. Appreciating 2:

II.2.1 Plea (document junction)

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It also intends to aggravating the addition of a document that claims to be placed in the file.

Pursuant to art. 706º paragraph 1 of CPC, documents can be attached to the allegations in exceptional cases to which refers art. 524º or if the joint only if made necessary by the judgment handed down in the 1st instance. The supervening documents can be together even begin visas to judges, which does not happen in this case.

It is assumed that the objective of the appellant is to strengthen the Court's attention to the opinions it now joins, since it expressly states that they are already in the file.

In this sense, whether understand that justification does not exist legally justified, whether they understand that it is a useless act, does not admit the addition of those documents to the file.

II.2.2 Facts

As for the change of the facts - arts. 1, 8, 9, 15, 16 and 17 of the Base instructory

General considerations

Pursuant to paragraph a) of paragraph 1 of the Code of article 712º the decision of the 1st instance can be modified by the Court of Relationship "is the process contain all the evidence on which it based the decision on points of the facts in question or if, having occurred recording of evidence submitted, has been contested in terms of article 690º-A, a decision based on them uttered. "

Challenging, the appellants, the decision on the facts, the law requires them, as they themselves recognize the text of their claims and under penalty of rejection, these specify which "concrete points that they consider incorrectly judged "and, as well," the concrete means of constant evidentiary process or the registration or recording it held, imposing decision on points of fact challenged different from the defendant. "In the case of recorded testimony should also be indicated which technical support segment which are the elements that require different defendant's decision (Art. 685-B of the Code of Civil Procedure).

With these requirements, intended to prevent the plaintiff is limited to attack, generally and overall, the decision in fact, simply asking for a review of all the evidence produced at first instance, record that addition could be used by the parties only dilatory motives (Lopes do Rego, Comments to the Code of Civil Procedure, 1999, Coimbra, p. 465).

First and circumscribing the subject of this action to the challenge of the facts, since already begin by noting that in relation to the answer given by the national court to art. 15 of instructory base, already it will be said now that the appellants failed to meet the claim burden that falls on them, in accordance with art. CPC 685-B.

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Indeed, the text of the claims does not mention in this part of the application concerns, so this point, will not present the court know.

Instead, with regard to the other points have been challenged by way of appeal, was given to the content of the claims of the appellants, it is deemed not requiring greater justification the assertion that show fulfilled the requirements laid down in the two paragraphs of the aforementioned art. 685-B of the CPC: the points were indicated fact that they consider misjudged (arts. 1, 8, 9, 16 and 17 of instructory base).

With regard to the evidence on which the appellants base their challenge of the facts, although not are referred to expressly in the above conclusion, the truth is that they are They are identified in the respective claims.

[2] As noted the Supreme Court, "the specification of concrete evidential means contained in recording must be accompanied by an indication of where the aggravation those listed with reference to noted in the minutes, pursuant to art. 522-C, No. 2 Cod. Proc. Civil. [...] referred to in the specification numbers Previous does not have to expressly state the conclusions of the allegations, but may appear on the remaining part of the same grounds, provided that the conclusions clear and noticeable reference to those specifications, so that the appellate court can safely realize if the resource object's boundaries. "

Previously, it was understanding that Court that "in the case of a afirmatório burden will have to be satisfied in the wording of claims, and that article 690ºA (now repealed by Decree-Law 303/2007, of Aug. 24) not even make mention of the mandatory findings show. And although it is understood by the general principle in Article 690º insito that the applicant, when contest the facts of the case, is not dispensed to formulate conclusions, they may only have the effect of limiting, accurately and synthetic, the object [3] resource, identifying the issues that it is intended to see discussed. "

The instant case

Overcome this issue of a formal nature, we will pass to the possibility of altering the decision of the matter fact by the court, which, except for its own motion issues, is limited by resource conclusions and thirst for review of the decision on the facts on the basis of witness testimony, its review is limited to the facts specifically invoked unless, in accordance with paragraph 4 of Art. 712 of CPC, there are grounds for greater intervention.

Thus, the ad court who is unable to consider any other issues not touched on the findings the appellants, although versed in the claims themselves. Therefore, in the event it is found, on appeal, any conclusive gap, this will be enough to derail, without more, the inquiry on

[4] its decision.

On the other hand, contrary to what happens to the facts, the appellate court is not limited to the consideration of evidence specifically indicated and can meet its own motion the other evidence and can not fail to consider those in which the contested decision was based. However, before we proceed to the analysis of applicants' claims, always tell you that the appeal against the decision on the facts does not, directly relates to the reevaluation of the evidence and developing a

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that decision corresponds to the conviction founded on it, as if it were the first decision: instead, the that material resource has the sole object of the judgment that the contested decision has been made of the facts data as proven.

Thus, regardless of the basis of the challenge, the decision on the facts may be changed only if a reassessment of the evidence has laid and if you have an error in judgment been identified or [5] [6] inconsistency between the striking evidence and such a decision.

Art. 1 of the Base instructory

In this case, the rebel is now appellants against the reply given by the first instance court art.

1 instructory the base, whereby it is inquired if found and characterized as described in the text PT 94 306 "a new substance" - the monosodium salt of alendronic acid in its trihydrate form, having the court quo completed, the evidence produced "which is only described in the text of a substance EN 94 306 - salt alendronic acid monosodium trihydrate on its way" - cfr. response to the facts of pgs. 1555 of autos.

It based court is your answer in statements given by the witnesses P, G, B, H and E which, according to the conviction of the court, were "in agreement at this point": that is, all said that the way monosodium trihydrate salt of alendronic acid has been described first in GB

In turn, the applicants claim that it could not have considered the court as unproven the novelty of substance, while in response to art. BI 35 refers to the result of the process described in aforesaid patent as being a crystalline product new and free of moisture.

Unless all due respect, it seems to me that, on this point, we are faced with a noticeable error in judgment the appeal court, even if the reference to "new substance" and "new product" coincide.

Moreover, by attacking this point of fact, the applicants now seek to extract a conclusion that no doubt goes beyond the facts that is whether the underlying active substance to patent set or not a new substance, patentability requirement.

That is, being concerned, in this case, if the patented process does not occur or the requirements of novelty and inventive activity, which the inventor to protect and make the act of right protection afforded by issuance of the patent, the classification as a substance as "new" or not, always run an analysis the entire constant evidential matter of the case, consisting of a single non matter of fact.

In the inventions of chemical and pharmaceutical products, in general, indicates the group of substances that define and are given examples for some of these substances.

[7] As indicated in the Value Judgment of Court, 14.12.2004 "preparation of chemical compositions and drug is made, it can be said, almost invariably by known processes because the inventor is limited to mixing and reacting the active substance (new or known) with other known active substances or auxiliary substances or carriers, also having nothing unique in itself, the process of obtaining the composition chemical or pharmaceutical. Now, therefore, if the active substance is known, the process of obtaining the composition - finished product - can not be protected, for lack of novelty. In fact, all products which are reacted

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They are known. And the very final result, the composition, is also known. If the active substance is new, the Process novelty consists in the choice of reaction media in which the active substance enters the new".

Accordingly, and bearing in mind that the appeal of the decision on the facts does not have the direct object, the re-evaluation of the evidence and the drafting of a decision corresponding to the conviction that founded it, as if it were a first decision, but rather the judgment that this point has been made of the decision

[8] defendant understands this court there were no grounds to proceed with the amendment of the decision of the matter Indeed, with respect to this part.

Art. 8 of the Base instructory

Questioned in the art. Instructory 8 of the base, the fact that the monosodium salt molecule has three molecules of Water does not add anything to their therapeutic action.

To this question answered in the affirmative the national court is considering as proven the existence of three water molecules add nothing to the therapeutic action of the substance and the reasons that his belief in produced testimonial evidence, particularly in the witness testimony M, B, H and P

Rebel against this decision to the appellants now claiming, in short, that through the proof of this is intended, fallacious, compare the monosodium salt of alendronic acid with the crystalline monosodium salt trihydrate alendronic acid, where the first, contrary to this, not intended for therapeutic purposes.

It seems, however, that with this claim, claim, the appellants, see judged as proven facts that have not been previously claimed by them, how could it have been, under art. 264, paragraph 3 of the Civil CP. On the other hand, the wording of Article instructory the base, it does not appear that the question pass by any comparison / difference between alendronic acid and alendronate.

The formulation of this question of reading and considering the matter on the record, it was intended, with the response to even judge whether the file to which it relates to EN 94306 and in particular the addition of three water molecules to

compound resulted in a change or no therapeutic action of the end product, and if so, such could lead us to conclude that we are facing a new product.

On the other hand, given the testimonial evidence produced in the records and the judgment of it extracted by the national court, not it seems there are reasons justifying the change in its response to the extent that witnesses surveyed were unanimously concluded that the therapeutic action is derived exclusively from the alendronic acid and substantially improved their performance, meeting the new storage and processing properties discovered through the use of monosodium salt trihydrate.

On the other hand, such witnesses still conclude that the molecule in question is, in chemical terms, always thereof, contributing the addition of said three water molecules solely for the commercialization substance.

Thus, also in this regard and there are no elements in the file that, by itself and by recourse to the rules of science, logic and experience, impose a different decision, must be rejected, as regards to this part, the request of the appellants.

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As to the question 9

The first instance court found no proof that PT reveal and demonstrate that the process claimed leads to formation of a free flowing powder, sustained as the 2nd claim, formulated by R. M with the INPI.

As a second demand made within the scope of said patent, the compound characterized in that the Crystalline trihydrate of monosodium salt of 4-amino-1-hydroxybutylidene-1,1-bisphosphonic acid, is characterized in that as a free flowing powder.

Questions remain not stated expressly that such the formulated CLAIM. However, the facts carreada to the file does not seem to exist elements that allow us to conclude that the national court, the consider as unproven the matters of the item in question, has incurred an error of judgment or there is no contradiction between the answer given to this article and the one given to Article 35 of the bi The fact that the court be considered as proved that the crystallinity and the absence of moisture to give important new product flow properties in the area of pharmaceutical formulation does not mean that this fluidity translates into the formation of a powder that allows it to flow freely. Indeed, only one proved clear increased flow by use of the patented process according to EN

Accordingly, also unfounded the applicants' request in this part.

Arts. 16 and 17 BI

By including in instructory basis, the matters of the questions 16 and 17 meant the national court, for one hand, establish a connection between the goods claimed in PT and IT, questioning about whether identity between the respective active ingredients and industrial application (Art. 16) and, if so, whether single point where the products differ is in the trihydrate form in which the active ingredient arises - (Question 17).

For these two points, understood the appeal court that turned out, accurately, that the principle and pharmaceutically acceptable active industrial application of the claimed products in PT ... are the same .. for one of the products covered by it .., also considering as proven that the only point wherein the two patents is the differ trihidrata form in which the active ingredient arises.

They claim the applicants herein that, as the patent IT .., And not only claim to compound formulations, whereby You may not cover the PT product ... or they have the same industrial application, given that that alendronate does not have this option.

As apparent from the tested matter in patent IT is described and claimed that the alendronic acid and its salts have therapeutic efficacy and can be used as active substances in medicaments for the treatment of bone diseases, with greater efficacy and lower incidence of side effects than other substances known to date of deposit, all claiming to be also in the aforesaid patent a process of Preparation of target biosfónicos acids, among which stands out alendronic acid or salts Pharmaceutically acceptable.

On the other hand, like the previously mentioned regarding the analysis given the challenge response On 15/16

by the national court to the matters of art. 8 and the other statements evidence in the file, left no doubt that the pharmaceutically acceptable active ingredient and present in both patents is the alendronic acid, generally given in the form of alendronic salt.

Incidentally, it is also clear the matter proved that the patent ... PT. uses similar to the process described and ... claimed in IT., an amino acid, phosphorous acid, phosphorus trichloride and also makes the hydrolysis product obtained may be carried out in the presence of a solvent (or diluent). This part not only has not contested, as itself down, without any doubt, the connection between the object of these two patents.

Hence we see reason to change the answer given by the national court, also in this part.

II. enjoying:

Not having been received, the challenge deduced towards changing the first instance as the committee Indeed, we are led to conclude that the rejection of the argument of the appellants.

In the present case the facts point in the direction that we are faced with the addition of three water molecules to a compound - keeping the active ingredient. However, this addition only allows the marketing of the substance, not changing the substance itself. In the absence in the record any elements which, by itself and by recourse to the rules Science, logic and experience show that the addition of these three water molecules that compound

entailed an amendment to the therapeutic action of the final product, it is not logical to conclude that we are facing a New product. Therefore, and in accordance with the proven facts do not seem acceptable are of the view that before a true invention that enjoys legal protection.

In light of the Industrial Property Code applies (1995), the patentability requirements of a particular intellectual creation are: the invention, novelty, inventive step and industrial applicability susceptibility and the permissibility (Article 47).

The news means that "is not known in the prior art - not disclosed so as to be understood [9] and operated by the skilled worker. "

The inventive step involves "an important qualitative leap, due to the author's own intellectual effort in order to stand out from the normal technical progress ". Oliveira Rise, alludes to the worthiness or inventive character, in the sense that the invention, in addition to the non-disclosure must "go beyond the obvious," what is meant by the demands that creativity requires. Otherwise we are facing a discovery, and not before an invention subtracted the desired protection.

In any case, the action also can not be accepted by the constant reasons for the decision rationale defendant, which appear to be the correct and that we are here by reproduced in full, considering harmed the questions it not known, which would result in a useless act.

III. For these reasons and in accordance with the legal provisions cited, refuses dismissed the appeal and confirmed the contested decision.

Costs for the appellant.

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Given the joint document of the death of the distinguished representative of appellant, in accordance with the provisions of Art. 276/1 / b) CPC states is suspended instance.

Lisbon, January 26, 2010

Maria Amelia Ribeiro

Graça Amaral

Ana Resende

[1] References in the submitted claim, the n. ° 15 of instructory basis, resulted from mere lapse

[2] Judgment of 30-10-2007, available on the site www.dgsi.pt.

[3] Article "The burden of compliance with the specification of the specific points challenged fact, referred to in point c) of 690º-A CPC, does not require the use of sacramental formulas, considering sufficiently satisfied when the the claim content leaves no doubt about the concrete issues of fact that the applicant claims to see revisited. "- B.C. the Supreme Court of 06.02.2008 (R. 3525/2007), available at www.dgsi.pt/jstj.nsf site.

[5] See Judgment of the Lisbon Relationship 01.03.2007.

[6] In this sense it ruled the Lisbon Court of relationship in its judgment of 12.06.2007.

[7] www.dgsi.pt Rel .: Des. Maria do Rosario Morgado, available on the site.

[8] This view emphasizes very clearly the provisions of b) and c) of paragraph 1 of Article 712 of the CPC, to constrain modification of that judgment at first instance the existence of elements which, by themselves, impose different decision made. Thus, the conviction of the judge shall in principle sindicável unless to demonstrate that, in their training, if violated rules of rationality and logic (of evidence law rules or the existence of any logic error or deviation from the rules of common experience).

[9] Ac. RL 30.09.2004, Des. Fatima Galante in Jusnet.