# **UJUB**

# 4th Mock-trial

International Chamber Paris Commercial Court (Chambre internationale du tribunal de commerce de Paris)

1, quai de Corse (île de la Cité), Paris

Monday 21 November 2022 13:00- 18:00

# **Cast and crew**

# The court

Dr Klaus Grabinski (DE)

Ms Camille Lignières (FR)

Mr Patrik Rydman (SE)

Presiding judge

Legally Qualified Judge

Technically Qualified Judge

# **Claimants' representatives**

Mr Jean-Hyacinthe de Mitry
Mr Pierre-Yves Demaure
Ms Mathilde Rauline
Gide Loyrette Nouel
Atout PI Laplace
Sanofi

# **Defendant's representatives**

Ms Pauline Debré
Mr Oliver Tischner
Lavoix
Mr François Rivière
Linklaters
Lavoix
L'Oréal

#### Witness

Mr Philippe Bessière Pierre Fabre

# Public's deliberation director

Ms Nathalie Sabotier Member Drafting Committee UPC Templates

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# **Organization committee**

Mr Thierry Sueur

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Ms Marie Bréchant

UJUB president

UJUB Advisor

ASPI president

AAPI president

CNCPI president

UJUB treasurer

CNCPI legal director

# **Storyboard**

Marseille is the sunniest French town. Inspired by its great weather, l'Université des Sciences de Marseille pioneers researches on solar energy. Further to the success of their solar plane, they decided to take up a new challenge: allowing each home to produce its own solar energy, at least for people lucky enough to live in the south of France. After a market study, they discovered that the photovoltaic panels were not a success since they disturb the appearance of the buildings. Therefore, they had the idea to create photovoltaic roof tiles.

Since they had no expertise in tiles, they partnered with an Italian start-up La Nuova Tessera which has just invented the green tiles (tiles coated with vegetal).

M. Gaspard Montretou Professor at the University and consultant for La Nuova Tessera took the lead in the project.

They invented a roof tile comprising a transparent cover and a solar collector.

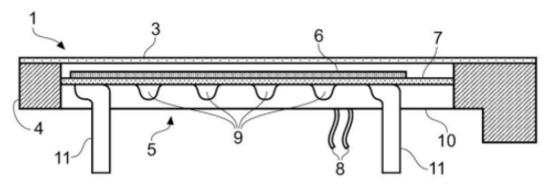
On October 14, 2017, La Nuova Tessera was an exhibitor at the Batomat fair. They sent emails to their clients announcing their participation at the fair and proudly promoting their new photovoltaic roof tiles. The emails comprised a link to a video on Youtube explaining briefly the functioning of the photovoltaic roof tile and indicated that one of the inventors, M. Gaspard Montretou, would be present at Batomat together with a prototype and happy to answer any question. The exhibition was a great success, and a lot of prospects were interested in this innovation.

They filed a EP patent application on November 21, 2017 and the patent was granted on December 11, 2019 under No EP 2 305 607 B1. No opposition has been filed. The patent is validated in France, Italy, Luxemburg, Cyprus and Portugal.

The

The first claim of the patent reads:

1. A roof tile (1) comprising a solar collector (5) and a transparent cover (3) having a solar direct transmittance above 91.0 %, wherein the solar collector (5) comprises a metal plate (7) and a fluid-tight passageway (9) for fluid, characterized in that the metal plate (7) is arranged between the transparent cover (3) and the fluid-tight passageway (9) in such a way that the heat can be transferred from the metal plate (7) to the fluid.



Université des Sciences de Marseille and La Nuova Tessera entered into a co-ownership agreement which namely prohibits one co-owner to launch any action relating to the patent without the other co-owner.

In October 2023, the Université des Sciences de Marseille became aware that Bad-glass a brickdury company with registered headquarters in Tiledavia was promoting at Batomat 2023 a transparent cover which could be assembled with a solar collector to obtain a photovoltaic roof tile. The University obtained the right to perform a saisie-contrefaçon during the Batomat exhibition and then launched an infringement action of the French part of the patent against Bad-glass. Because they had to take all these decisions in a very short period of time since Batomat 2023 was about to close, they forgot to inform their Italian partner. The infringing action is pending before the Paris Tribunal judiciaire. In defence, Bad-glass asked for the cancellation of the French part of the patent without serving any intervention writ of summons against La Nuova Tessera. The oral hearing is scheduled on March, 4 2025.

In March 2024, La Nuova Tessera discovered some transparent covers made by Bad-glass, and sold to a tile manufacturer called "The Tuilerie" in Luxemburg that is manufacturing and distributing a roof tile according to the patent comprising a solar collector and a transparent cover. The transparent glass covers The Tuilerie purchases from Bad-glass have a solar direct transmittance of 91.5%. On their website, Bad-Glass explains that the main use of their glass covers is photovoltaic tile but they can also be used for windows.

The Tuilerie is a client of La Nuova Tessera distributing their green tiles.

La Nuova Tessera informed the Université des Sciences de Marseille and they decided to launch together an infringement action against Bad-Glass for all the designated countries in front of the Central Division of UPC based in Paris.

La Nuova Tessera and the Université des Sciences de Marseille are claiming for an injunction against Bad-Glass in all countries where their patent is validated together with damages.

In defence, Bad-Glass is asking the UPC to stay the proceedings until the decision of the Paris *Tribunal judiciaire* (in the framework of this mock trial, which is supposed to take place in one single hearing, it has been agreed that this request for the stay of the proceedings would be dealt with by the court during the final hearing and not as a preliminary objection under Rule 19; it will be made clear, during the presentation of the case, that, in the real life, a request for the stay of proceedings based on a *lis alibi pendens* is likely to be considered as "concerning the jurisdiction and competence of the Court" and, as such, should be raised by way of a preliminary objection within one month of service of the Statement of claim under Rule 19).

As a subsidiary claim, Bad-Glass lodges a counterclaim for the invalidity of the patent for lack of novelty because of its disclosure at Batomat on October 14, 2017 and argue that there is no infringement.

In its reply, l'Université de Sciences de Marseille clarifies that it maintains the proceedings it brought before the Tribunal judiciaire de Paris in 2023 for the facts mentioned in its statement of claim before this Tribunal and, accordingly, that it excludes those facts from the proceedings before the UPC.

La Nuova Tessera and l'Université de Sciences de Marseille further files a statement from M. Gaspard Montretou explaining that the Youtube video only showed combination of a roof tile (1) comprising a transparent cover (3) and a solar collector (5). However, there was no explanation of the internal features of the roof tile. M. Gaspard Montretou also stated that even if a maquette of a building with the roof tile was shown at Batomat 2017, it was put on a nice display under a glass dome that everybody could see from 1 meter but could not touch and with no possibility to see the metal plate and the fluidetight passageway and notably how the heat can be transferred from the metal plate (7) to the fluid. Some prototypes of the roof tile were also exhibited.

M. Gaspard Montretou will be heard as a witness during the oral hearing.

# Schedule of the mock trial proceedings

15/05/2024	Statement of claim by Université des Sciences de Marseille and La Nuova Tessera
15/07/2024	Statement of Defence and Counterclaim for Revocation by Bad-Glass
15/09/2024	Defence to the Counterclaim for Revocation and Reply to the Statement of Defence by Université des Sciences de Marseille and La Nuova Tessera
15/11/2024	Rejoinder to the Reply by Bad-Glass
21/11/2024	Notional date of the mock trial

# **Documents of the mock trial proceedings**

### **Statements**

```
2024-05-15_Statement_of_claim
2024-07-15_Statement of Defense & counterclaim for revocation
2024-09-15_Reply_to_Statement_Defence
2024-11-15_Rejoinder to the reply
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### **Exhibits**

# **Claimant Exhibits**

```
CLAIM_Exhib_1_EP_2_305_607
CLAIM_Exhib_2_-_Invoice
CLAIM_Exhib_3_-_Bad_Glass_Website
CLAIM_Exhib_4_-_Report_on_the_Tile
CLAIM_Exhib_5_-
_Excerpt_of_the_handbook_of_Düsseldorf_Appeals_Court_Judge_Kühn en
CLAIM_Exhib_6_-_Opinion_advocat-
general_MSD_v._Teva_6_June_2017_(English_translation)
CLAIM_Exhib_7.1_-_Com_8_juin_2017
CLAIM_Exhib_7.2_-CA_Paris_4_mars_2009_FR
CLAIM_Exhib_7.2_-CA_Paris_4_mars_2009_EN
CLAIM_Exhib_8_-_Affidavit_of_Gaspard_Montretou
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# Respondent\_Exhibits

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RESP_Exhib_01_Email_from_La_Nuova_Tessera
RESP_Exhib_02_Video_from_La_Nuova_Tessera (place_holder)
RESP_Exhib_02bis_Bailiff_Report
RESP_Exhib_03_Affidavit_Ms_Martin
RESP_Exhib_03bis_Affidavit_Ms_Martin_updated
RESP_Exhib_04_Doctrine_on_the_jurisdiction_of_the_UPC
RESP_Exhib_05_Commercial_email_to_Mr_Truth
RESP_Exhib_06_YouTube_Help
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# STATEMENT OF CLAIM

# FOR:

- 1. UNIVERSITÉ DES SCIENCES DE MARSEILLE établissement public à caractère scientifique, culturel et professionnel, registered under SIREN number 123 456 789, whose registered office is located avenue des Prix Nobels, in Marseille, France, represented by its President
- **2. LA NUOVA TESSERA,** a company registered under the laws of Italy, whose registered office is located soleggiata strada piastrellata, in Tiramisu, Italy, represented by its CEO,

#### Represented by:

the-mock.Paris

# Jean-Hyacinthe de Mitry

Advocate, admitted to the Paris Bar GIDE LOYRETTE NOUEL A.A.R.P.I. 1340 rue de l'ordre des avocats, 75001 Paris (France)

Jean-Hyacinthe.de-Mitry@for-

#### **Pierre-Yves Demaure**

Conseil en propriété industrielle, European Patent Attorney ATOUT PI LAPLACE 1973 chemin de la CBE, 35000 Rennes (France) Pierre-Yves.Demaure@for-themock.Bretagne

#### **Mathilde Rauline**

European Patent Attorney SANOFI 1883 rue de la convention de paris, 63000 Clermont-Ferrand (France) Mathilde.Rauline@for-themock.Auvergne

#### **VERSUS**:

**BAD GLASS**, a company registered under the laws of Tiledavia, whose registered office is located Penitentiary road, in Conspiracy, Tiledavia

#### **MAY IT PLEASE THE COURT**

(1) Université des Sciences de Marseille and La Nuova Tessera (together the "Claimants") seek judgment against the Tiledavian company Bad Glass ("Bad Glass") for infringing the European patent EP 2 305 607 B1 ("EP'607" or the "Patent").

#### 1. FACTS AND PROCEEDINGS

(2) Université des Sciences de Marseille (the "**University**") is a French University having a pioneering research department in solar energy.

La Nuova Tessera is an Italian start-up company which has invented "green" tiles, namely tiled coated with vegetal.

(3) The Claimants worked together to design a new roof tile comprising a transparent cover and solar collector.

In this respect, they are joint proprietors of the European patent EP2305607 B1 (exhibit 01), which was applied for on 21 November 2017 and granted on 11 December 2019, with effect for France, Italy, Luxembourg, Cyprus and Portugal (the "Territory").

No opposition has been filed and all annuities have been duly paid.

(4) In October 2023, the University became aware that Bad-Glass, a brickdury company headquartered in Tiledavia, outside the territory of the UPC Contracting Member States, was promoting at Batomat 2023, an exhibition in France dedicated to construction, a transparent cover which could be assembled with a solar collector to obtain a photovoltaic roof tile.

The University performed a *saisie-contrefaçon* during Batomat 2023 and then launched an infringement action of the French part of its patent against Bad-Glass, which is pending before the Paris first instance court (*Tribunal judiciaire*). In defence, Bad-Glass asked for the cancellation of the French part of the patent. The oral hearing is scheduled on March, 4 2025.

- (5) The Claimants reasonably thought that, as a result, Bad-Glass would stop pursuing its infringing acts but, in March 2024, La Nuova Tessera discovered some transparent covers made by Bad-Glass, and sold to a tile manufacturer in Luxemburg called The Tuilerie, which is manufacturing and distributing a roof tile according to the Patent.
- (6) As per Art 33.1 of the Agreement on a Unified Patent Court ("**UPCA**"), the Claimants decided to launch this infringement action before the Paris seat of the UPC Central Division due to the facts that (i) Luxemburg neither host a local division nor participate in a regional division and (ii) the Patent is classified "E" under the International Patent Classification.

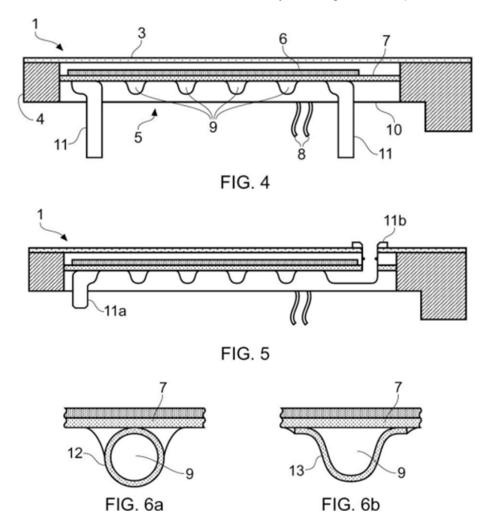
As per Art. 49.6 UPCA, the language of proceedings is English, as it is the language in which the Patent was granted.

(7) The fixed fee of 11.000 € according to Rule 370.2(a) and the value-based fee of EUR 13,000 (the Claimants assess that the value of the case is comprised between EUR 2,000,000 and EUR 3,000,000 as further explained below in section 3.2) have been paid together with the filing of this infringement action (Rule 370.1(p)).

#### 2. INFRINGEMENT

# 2.1 Claim analysis

- (8) The patent at issue concerns a roof tile (claim 1 to Claim 6) and a solar collector (claim 7).
- (9) The roof tile (1) according to the invention comprises a transparent cover (3) for admitting solar radiation into the roof tile. It is illustrated notably in the figures 4-6 reproduced below:



(10) In order to increase the amount of heat that enters the tile, the transparent cover (3) has a solar direct transmittance higher than 91.0%.

#### 2.2 Indirect infringement

#### **2.2.1** Facts

(11) Bad-Glass sells transparent covers to customers (**exhibit 02**). According to its website, these transparent covers have a solar direct transmittance of 91,5% (**exhibit 03**).

Bad-Glass website mentions that the transparent covers are suitable for covering photovoltaic tiles (exhibit 03).

These transparent covers are then assembled by third parties with tiles, following the instructions of Bad-Glass website (exhibit 03).

(12) Article 26 UPCA gives the right to prevent the indirect use of a patented invention. As will be apparent from the analysis below, Bad-Glass transparent covers fulfill all the criteria.

# 2.2.2 Reproduction of claim 1 and claim 3 combined with claim 1

Claim 1	Analysis of Roof tiles	
A roof tile (1)	Bad-Glass encourages its transparent covers to be disposed on roof tiles (exhibit 03)	
comprising a transparent cover (3) having a solar direct transmittance higher than 91.0% (5)	Bad-Glass transparent covers have a solar direct transmittance of 91,5% (exhibit 03)	
and a solar collector, wherein the solar collector (5) comprises a metal plate (7) and a fluid-tight passageway (9) for fluid, and wherein the metal plate (7) is arranged between the transparent cover (3) and the fluid-tight passageway (9) in such a way that heat can be transferred from the metal plate (7) to the fluid	Examples of roof tiles from The Tuileries, on which the Bad-Glass transparent covers are assembled, reproduce all these characteristics (exhibit 04)	

Claim 3	Analysis of Roof tiles	
A roof tile (1)	Bad-Glass encourages its transparent covers to be disposed on roof tiles (exhibit 03)	
Wherein the solar collector (5) comprises a photovoltaic module (6) mounted on the metal plate (7)	The main use of Bad-Glass transparent covers is photovoltaic tile. (exhibit 03)  Examples of roof tiles from The Tuileries, on which the Bad-Glass transparent covers are assembled, reproduce all these characteristics (exhibit 04)	

(13) All features of claim 1 and 3 are reproduced.

#### 2.2.3 All conditions of Article 26 UPCA are met

One of the key conditions of Article 26 UPCA is the requirement that the supplied means shall relate to an "essential element of the invention".

Given that this article derives almost literally from the national legislation of Contracting Member States, including France, Germany and the Netherlands, it is interesting to compare the case law in these three countries and see that they have the very same approach consisting in ruling that, as soon as the element is claimed (Germany), or participates to the result (France), or is offered (Netherlands), the requirement of "essential element" is fulfilled.

(15) According to German case-law:

"As a rule, an element of the invention is already essential if it is part of the patent claim. It does not matter whether the means in question (merely) appears in the generic term of the patent claim or whether it is mentioned in the characterizing part of the patent claim and thus distinguishes the subject matter of the invention from the prior art" (Handbook of Düsseldorf Appeals Court Judge Kühnen (translated) - exhibit 05).

- (16) According to Dutch case-law, which is best explained by the opinion of the advocate general in 2017 Teva/MSD decision on ribavirin:
  - "6.3: The concept of 'essential element' is not limited to an element that is in itself new and inventive. 6.4: What matters, however, is whether 'means' ('relating to an essential element of that invention, for putting it into effect therein') are offered or supplied by Teva" (Opinion advocate general, MSD v Teva, 6 June 2017 exhibit 06).
- (17) Finally, according to French case law, "an element that participates in the claimed result constitutes an essential means" (Cass. com. 8-6-2017, n° 15-29.378 and CA Paris 2007/08437 of 4 Mar 2009 exhibit 07).
- (18) This being recalled, the table reproduced below shows that Bad-Glass infringes indirectly the Claimants' patent as per Article 26 UPCA.

Article 26 UPCA	
(1) A patent shall confer on its proprietor the right to prevent any third party not having the proprietor's consent	Bad-Glass does not have the consent of any of the patentees
from supplying or offering to supply, within the territory of the Contracting Member States in which that patent has effect	Bad-Glass supplies at least in Luxembourg, where the Patent has effect
any person other than a party entitled to exploit the patented invention, with means, relating to an essential element of that invention,	The transparent cover with the claimed solar direct transmittance is an essential element of the invention, which is referred to both in the preamble and the characterizing part of the Patent, and without which Claim 1 would not exist
for putting it into effect therein, when the third party knows, or should have known, that those means are suitable and intended for putting that invention into effect.	Bad-Glass encourages on its website its transparent covers to be assembled with roof tiles according to the patented invention (exhibit 03). In addition, the Claimants previously sued Bad-Glass for patent infringement in France, based on the same patent and in relation to neighboring facts.
(2) Paragraph 1 shall not apply when the means are staple commercial products, except where the third party induces the person supplied to perform any of the acts prohibited by Article 25.	The transparent covers are not made with usual glass: they have a reduced amount of iron (preferably below 0.01%wt), and chemical oxidizers (description [017]).  Therefore, they are not staple commercial covers, and Bad-Glass induces the tiles manufacturers to perform acts prohibited by Art. 25 UPCA
(3) Persons performing the acts referred to in Article 27(a) to (e) shall not be considered to be parties entitled to exploit the invention within the meaning of paragraph 1	Bad-Glass does not fall into any of the limitations of the effects of a patent envisaged in Art 27 (a) to (e) UPCA

#### 3. RELIEF AND REMEDIES

#### 3.1 Injunction and corrective measures

- (19) As Bad-Glass has infringed the Patent, the Court will grant the Claimants' application for a permanent injunction limited to the use of Bad-Glass's transparent cover for tiles, as further detailed in pages 7-8 of this statement of claim.
- (20) Also, the infringement of the Patent has depreciated the Claimants' highly innovative character in the eye of the public. Therefore, the Court will also order the publication of the upcoming judgment, as further detailed in pages 7-8 of this statement of claim.

#### 3.2 Provisional damages and right to information

- (21) It is clear that, as provided in Article 68(1) UPCA, Bad-Glass infringes the Patent knowingly since the University had, prior to launching this action, launched against Bad-Glass a patent infringement action before the Paris first instance court (*Tribunal judiciaire de Paris*) based on the Patent and relating to neighboring infringement acts.
- (22) This specified, the Claimants' loss is firstly the result of the violation of the exclusive rights that they own in the Patent. The rights in a patent are absolute proprietary rights. Accordingly, any infringement of the patent is injurious in itself and therefore merits relief.

Also, infringing the Patent has allowed Bad-Glass to save on significant intellectual and tangible investments because it has not had to develop its own product.

Finally, according to its website, Bad Glass has covered at least 1,000 buildings with solar tiles comprising its transparent cover (**exhibit 03**). The Tuileries purchases these transparent covers at 200 € / m² as evidenced by **exhibit 02**. A mean roof surface (taking into account houses, apartment buildings and commercial buildings) is 250 m² in Europe. An arm's length license fee in the field is 5%.

Therefore, the estimation of the license fee lost by the Plaintiff is:

200 (price per  $m^2$ ) x 250 (mean surface of a roof) x 0.05 (license fee) x 1,000 (number of buildings) = **EUR 2,500,000** 

(23) For this reason, the Claimants request that the Court order an interim award of damages under Rule 119, in the amount of **EUR 250,000**, and that the final amount of damages be set in separate proceedings, once Bad-Glass has provided the Claimants with the information detailed in pages 7-8 of this statement of claim, back to five years from the service of this statement of claim, as per Articles 67 and 72 UPCA.

### 3.3 Costs and court fees

- (24) The Claimants have been obliged to bring legal action to enforce their interests before this Court, whereas Bad-Glass could have stopped, or at least suspended, its illicit behavior after the start of the case in France. It would, accordingly, be inequitable for them to have to assume liability for costs they have been compelled to incur in doing so.
- (25) Therefore, Bad Glass should be ordered to reimburse to the Claimants all legal costs they have incurred, in the amount of EUR 400,000 since the value of the case is comprised between EUR 2,000,000 and 3,000,000, and all court fees.

\*

### WHEREFORE

Having regard, *inter alia*, to Articles 26, 63, 64, 67, 68, 69, 70 and 72 of the Agreement on a Unified Patent Court;

Having regard to the exhibits listed in the schedule attached hereto;

We pray this Court:

- (1) **TO RULE** that Bad-Glass has committed and are committing infringements of claims 1 to 7 of the European patent EP 2 305 607 B1 owned by the Claimants;
- (1) **TO PROHIBIT** Bad-Glass from committing any infringement of the European patent EP 2 305 607 B1 in the Territory, in any manner and for whatever purpose whatsoever, directly or indirectly through any proxy or agent, whether natural person or corporate entity, subject to a non-compliance penalty of ten thousand (10 000) euros per disputed product and per day, to be effective eight (8) days after service of the upcoming judgment;
- (2) for doing so, **TO ORDER** Bad-Glass to provide the following statement on each instance it provides information on its transparent cover in or for the Territory, being it on a website, on the boxes protecting the transparent covers, on any leaflet present with the transparent cover, in any fair or professional event, or via any other means and in every other instance: "the use of this transparent cover on roof tiles has been recognized to infringe patent EP 2 305 607. You are encouraged to contact the patentee for discussing license conditions should you wish to use this transparent cover on a roof tile";
- (3) **TO ORDER** Bad-Glass, subject to a non-compliance penalty of ten thousand euros (€ 10 000) for each day's delay in doing so once thirty (30) days have elapsed since the service of the upcoming judgment, to disclose the following to the Claimants:
  - the origin and distribution channels of the infringing products, including the names and addresses of the manufacturers, suppliers, importers, exporters, distributors and other holders of the infringing products in the field of roof tiles;
  - the documents, in particular purchase orders, delivery notes, invoices, sales records and inventory statements, proving the number of infringing products manufactured, imported, exported, delivered, marketed, received and/or ordered by any means into or from the Territory, together with the purchase and resale prices of these products and together with an indication of whether the products had a dimension suitable for being assembled with roof tiles; and
  - the identity of any third person involved in the production or distribution of the infringing products in the field of roof tiles;

for the avoidance of doubt, the information supplied shall be certified as true, accurate and complete by the statutory auditors of Bad-Glass and shall relate to the five years preceding the service of this statement of claim;

- (4) **TO ORDER** The Tuileries, subject to a non-compliance penalty of ten thousand euros (€ 10 000) for each day's delay in doing so once thirty (30) days have elapsed since the service of the upcoming judgment, to disclose the same items as those mentioned in paragraph (5) above to the Claimants;
- (5) **TO ORDER** an interim award of damages in the amount of EUR 250,000;

- (6) TO GRANT LEAVE to the Claimants to have, in the Territory, the judgment published in five (5) newspapers or magazines of their choice per country and at the expense of Bad-Glass, the cost of each insertion to be set at a maximum of five thousand euros (€ 5 000), excluding taxes;
- TO ORDER that the upcoming judgment be published in full at the expense of Bad-Glass in the form of a document in PDF format, reproducing the entirety of the decision, accessible via a clearly visible hypertext link situated at the top of the home page of each version of the website of Bad-Glass accessible in the Territory (or any other address offering access to such website(s)), the link to be entitled: "Bad-Glass has been ruled liable by the court for the infringement of a patent belonging to Université des Sciences de Marseille and La Nuova Tessera", in a font with a character size of at least twenty (20) points, for a period of six (6) months starting from the date it was first uploaded, subject to a non-compliance penalty of ten thousand euros (€ 10 000) for each day's delay in doing so on a per country basis, once eight (8) days have elapsed since the service of the upcoming judgment;
- (8) **TO ORDER** that, during two (2) years following the service of the upcoming judgment, Bad-Glass shall at each trade show of professional fair it will participate, affix above its stand or booth a panel that is no less large than 2m x 3m indicating visibly "Bad-Glass has been ruled liable by the court for the infringement of a patent belonging to Université des Sciences de Marseille and La Nuova Tessera", subject to a non-compliance penalty of ten thousand euros (€ 10 000) for each day's delay in doing so on a per country basis; and
- (9) **TO ORDER** Bad-Glass to reimburse to the Claimants all legal costs in the amount of EUR 400,000, and all court fees they have incurred.

# SCHEDULE OF EXHIBITS

No.	Description
1	Patent EP 2 305 607
2	Invoice of transparent covers from BadGlass by The Tuileries
3	Bad-Glass website, as appeared in March 2024 and still appears today
4	Analysis of a tile bought from The Tuilerie, comprising a transparent cover from Bad-Glass
5	Handbook of Düsseldorf Appeals Court Judge Kühnen
6	Opinion advocate general, MSD v Teva, 6 June 2017
7	Cass. com. 8-6-2017, n° 15-29.378 ( <b>7.1</b> ) and CA Paris, 4 March 2009 (2007/08437) ( <b>7.2</b> )

Filed on 15 July 2024 Case No. 2024-0099

# STATEMENT OF DEFENCE AND COUNTERCLAIM FOR REVOCATION

#### FOR:

**BAD-GLASS**, a company incorporated under the laws of the State of Tiledavia, Registration No. 2609567, having its head office at 54, Imagination road, 1227 Tiledavia, represented by its President,

Hereinafter the "Defendant"

#### Represented by:

Pauline Debré	Oliver Tischner	François Rivière
Linklaters LLP	Lavoix	L'Oréal
25, rue de la nouveauté –	2, place de l'activité	30, rue de l'invention –
75008 PARIS	inventive – 75001	92300 LEVALLOIS-PERRET
pauline.debre@mock.com	PARIS	francois.riviere@mock.com
	otischner@mock.eu	

#### **AGAINST:**

- (1) Université des Sciences de Marseille, établissement public à caractère scientifique, culturel et professionnel, registered under SIREN number 123 456 789, whose registered of fice is located at avenue des Prix Nobels, in Marseille, France, represented by its President.
- (2) La Nuova Tessera, a company registered under the laws of Italy, whose registered office is located soleggiata strada piastrellata, in Tiramisu, Italy, represented by its CEO.

Hereinafter together the "Claimants"

#### Represented by:

Jean-Hyacinthe de Mitry	Pierre-Yves Demaure	Mathilde Rauline
Gide Loyrette Nouel AARPI	ATOUT PI LAPLACE	SANOFI
1340 rue de l'Ordre des	1973 chemin de la CBE,	1883 rue de la Convention
avocats – 75001 PARIS	35000 RENNES	de paris, 63000
Jean-Hyacinthe.de-Mitry@for-	Pierre-Yves.Demaure@for-	CLERMONT-FERRAND
the-mock.Paris	the-mock.Bretagne	Mathilde.Rauline@for-the-
		mock.Auvergne

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The fixed fee of €20.000 for the counterclaim for revocation has been paid according to Rule 370.4(b).

#### MAY IT PLEASE THE COURT

#### 1 FACTS AND PROCEEDINGS

#### 1.1 Facts

- **1.** Bad-glass ("**Bad-Glass**"), is a company specialised in brickdury, having its head office at Tiledavia.
- 2. The Claimants, the Université des Sciences de Marseille (the "University") and the Italian start-up La Nuova Tessera ("La Nuova Tessera"), have both an expertise in solar energy. Their partnership led to the filing on 21 November 2017 of the patent EP 2 305 607 B1 (the "Patent") which covers roof tiles with solar collectors. This Patent was granted by the EPO on 11 December 2019 and is validated in France, Italy, Luxembourg, Cyprus and Portugal.

As will be demonstrated below, the Patent is invalid at least for lack of novelty.

# 1.2 Proceedings

3. In October 2023, the University was authorized by the Paris First Instance Court to perform a saisie-contrefaçon at Batomat 2023 and to seize transparent cover exhibited on Bad-Glass booth. Alleging that such covers would infringe the Patent, the University initiated an infringement action of the French part of the Patent against Bad-Glass before the Paris First Instance Court ("Tribunal Judiciaire"). In defence, Bad-Glass filed a counterclaim for revocation of the French part of the Patent.

The case is docketed under No. 23/00202 and the oral argument hearing is scheduled before the Tribunal Judiciaire on 4 March 2025.

4. By Statement of Claim dated 15 May 2024, the Claimants initiated another infringement action against Bad-Glass, this time before the Central Division, Paris Seat of the UPC. The Claimants argue that Bad-Glass would have committed infringement acts by selling transparent covers to the company "The Tuilerie" based in Luxembourg which manufactures and distributes a roof tile, that would, according to the Claimants, infringe their Patent.

#### 2 DISCUSSION

5. It will be first demonstrated below that the proceedings before the UPC should be stayed until a final decision is issued by the Paris courts (2.1). In the alternative, the UPC shall find the Patent invalid due to lack of novelty (2.2). In any event, the Patent is not infringed by Bag-Glass (2.3) and the requested measures shall be dismissed (2.4).

#### 2.1 In principle: the proceedings before the UPC shall be stayed

- 6. Article 71(c)(2.) of the Brussels I Recast<sup>1</sup> specifies that "Articles 29 to 32 of this Regulation shall apply where, during the transitional period referred to in Article 83 of the UPC Agreement, proceedings are brought in the Unified Patent Court and in a court of a Member State party to the UPC Agreement".
- **7.** Articles 29 to 32 of the Brussels I Recast define how courts of the EU member states should deal with proceedings involving *lis pendens* or related actions:

Regulation (EU) No 1215/2012 of the European Parliament and of the Council of 12 December 2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (recast)

- Article 29 provides that if proceedings involving the same cause of action and the same parties are brought in more than one Member State, any court other than the court first seized **shall** of its own motion stay its proceedings until jurisdiction of the court first seized is established.
- Article 30 indicated that if "related actions" are pending in the courts of different
  member states, any court other than the court first seized may stay the proceedings
  to avoid the risk of irreconcilable judgments from separate proceedings.
- **8.** In the present case, the requirements of Article 29 are fulfilled. Indeed, the proceedings involve:
  - the same cause of action: an alleged infringement of the same patent (French part of the Patent).<sup>2</sup>
  - the same parties: the University and Bad-Glass are parties to both proceedings.

Therefore the Court which was not seized first – the UPC – must stay the proceedings until a final decision is rendered by the Paris Courts. Such decision would be coherent with case-law of most State parties to the UPCA.<sup>3</sup>

9. Should the Court consider that the cause of action or the parties are not the same, it will in any case stay the proceedings based on <u>Article 30</u> of the Brussels I Recast because there is a risk of irreconcilable judgments.<sup>4</sup>

The situation of the UPC during the transitional period is unprecedented since during this time period, both national courts and the UPC will have jurisdiction to rule on infringement and validity of an EP patent and to order injunctions covering the same territories.

In a scenario where (i) the Tribunal Judiciaire would hold the Patent invalid and dismiss the infringement claims and (ii) where the UPC would hold the Patent valid and finds infringement, it is easy to understand that there would be irreconcilable judgments from separate proceedings, which is exactly the situation that the Brussels I Recast tries to avoid.

Indeed, the scope of the potential injunction that would be granted by the UPC would necessarily cover the French territory and would therefore directly contradict the decision of the Tribunal Judiciaire rejecting the claims. Similarly, the decision by which the UPC would reject the counterclaim for revocation for all territories, including France, would directly contradict the decision of the Tribunal Judiciaire.

Further, the stay would not be disproportionate as the decision of the Tribunal Judiciaire will likely be issued in less than a year, and the Tribunal Judiciaire will be able to rule on the alleged infringement committed in foreign countries.<sup>5</sup>

This is why the UPC will stay the proceedings.

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<sup>&</sup>lt;sup>2</sup> ECJ, 6 December 1994, Case C-406/92, pt. 38: "For the purposes of Article 21 of the Convention, the "cause of action" comprises the facts and the rule of law relied on as the basis of the action."

<sup>&</sup>lt;sup>3</sup> For example, French Supreme Court, 9 July 2014, No. 13-13.5351; French Supreme Court, 28 January 2015, No. 1324.742

<sup>&</sup>lt;sup>4</sup> ECJ, 6 December 1994, Case C-406/92: "It follows that the concept of related actions there defined must be given an independent interpretation. In order to achieve proper administration of justice, that interpretation must be broad and cover all cases where there is a risk of conflicting decisions, even if the judgments can be separately enforced and their legal consequences are not mutually exclusive."

<sup>&</sup>lt;sup>5</sup> French Supreme Court, 29 June 2022, No. 21-1.085

In application of the rules recalled above, the UPC shall stay the proceedings until a final decision is issued in France.

#### 2.2 In the alternative, the Patent is invalid

**10.** As will be established below, claims 1 to 7 of the Patent shall be revoked based on Articles 52 and 54(1) and (2) of the EPC.

#### 2.2.1 Applicable rules

- 11. An invention is only patentable if it is new (Art. 52 EPC), meaning if it does not form part of the state of art (Art. 54 (1)). The state of art comprises everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application (Art. 54(2) EPC).
- 12. It is considered that for an information to be available "to the public", it is sufficient that a single person be in a position to gain access to and understand it<sup>6</sup>, while such person is under no obligation to maintain secrecy.<sup>7</sup>

#### 2.2.2 The alleged invention

- 13. According to claim 1, the alleged invention consists of: "A roof tile (1) comprising a transparent cover (3) having a solar direct transmittance higher than 91.0 % and a solar collector (5), wherein the solar collector (5) comprised a metal plate (7) and a fluid-tight passageway (9) for fluid, and wherein the metal plate (7) is arranged between the transparent cover (3) and the fluid-tight passageway (9) in such a way that heat can be transferred from the metal plate (7) to the fluid".
- 14. It is explained ([9], [10] and Figure 3) that it was known to use a roof tile comprising a transparent cover 3, a frame 4 and a solar collector 5 which comprises a photovoltaic module 6, a metal plate 7 and electrical wires 8 and where the photovoltaic module 6 is mounted on the metal plate 7. The photovoltaic module 6 absorbs solar radiation and provides electrical energy via the electrical wires 8. It is further explained that the metal plate 7 (preferably made of a metal with a high thermal conductivity such as copper) "ensures that heat is dissipated from the photovoltaic module 6". Indeed, it is well known that "the efficiency of photovoltaic modules decreases as their temperature increases".
- **15.** Figure 4 shows a roof tile 1 according to the alleged invention. "<u>This roof tile 1 has improved heat dissipation</u>" thanks to the presence of fluid-tight passageway 9 which "follows a meandering path along the metal plate 7 "[11].

Therefore the essential features of the invention compared to the known roof tile is the association of the metal plate 7 with fluid-tight passageway 9 that ensure that the metal plate is able to conduct the heat but also to dissipate it so as to allow the solar collector to be more efficient.

The metal plate 7 is arranged between the transparent cover (3), which "protects the solar collector 5 from rain and dirt" [8] and the fluid-tight passageway (9). It is further explained that "in order to increase the amount of heat that enters the tile, the transparent cover (3) has a solar direct transmittance higher than 91.0%, preferably 91.5% or more" [17].

2.2.3 The alleged invention was made available to the public prior to the filing of the Patent

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<sup>6</sup> BGH x ZR, 116/14

<sup>&</sup>lt;sup>7</sup> Paris Court of Appeals, May 20, 1998, RDPI 1999, No. 99, p. 25; PIBD 1998, No. 663, III, p. 501

**16.** The alleged invention was made available to the public by La Nuova Tessera in the following disclosures:

Promotional email dated 25 September 2017 sent by La Nuova Tessera to its customers, without any mention "confidential"<sup>8</sup> The e-mail describes a tile comprising solar collectors - "photovoltaic roof tiles" comprising a transparent cover (3) of very high transparency of 91.5% (i.e. greater than 91%), protecting a solar collector.

Also this email reproduces Figures 1 and 2 of the Patent, notably showing the use of a frame (4) holding the solar collector (5). Figure 1 also discloses a solar collector system formed from a combination of a plurality of roof tiles (1).

According to the email, said tile is capable of heating a building or house thanks to "flat fluid-tight passageways" which are located behind the solar collector."

The presence and positioning of flat fluid-tight passageways is therefore disclosed.

A YouTube video<sup>9</sup> in which the CEO of La Nuova Tessera presenting their photovoltaic tiles accessible to all web users without restrictions through Google and still available online<sup>10</sup> The CEO of La Nuova Tessera explained that the main advantage of their new tiles compared to prior art is that the new products allow heat dissipation thanks to the use of an ingenious system using the passing of fluid to cool down the whole system and present the prototype, showing the metal plate with flat fluid-tight passageways below the transparent cover.

The exhibition of a maquette of a building with a roof tiles according to the invention at Batomat 2017<sup>11</sup>

The prototype was visible to a public of professionals at a distance of one meter i.e. allowing a clean, clear and precise observation of several tiles under a dome of glass.

In addition, it was not forbidden to take pictures, so that by zooming in it was possible to have an even clearer view of the different pieces of the prototype.

Notably, considering that the photovoltaic module mounted on the metal plate does not cover the entire surface of the said metal plate, and that such module was only covered by a very transparent glass cover, the structure and positioning of the metal composition of the metal plate could necessarily be seen by someone looking down at the prototype on the right and left side of the photovoltaic module.

The explanations given by the inventor (G. Montretou) at Batomat 2017 to the visitors, not bound by a confidentiality undertaking:

Professor G. Montretou has detailed the complete structure of the photovoltaic roof tile to the interested visitors. Indeed, G. Montretou could not resist replying to the classic question from the public "but how does it work?" and was happy to explain in detail the function of the tile, its structure and the means designed to achieve the object of the alleged invention.

<sup>&</sup>lt;sup>8</sup> Exhibit 1: Promotional email sent by La Nuova Tessera to its clients

<sup>&</sup>lt;sup>9</sup> Exhibit 2: YouTube Video and related bailiff report

<sup>&</sup>lt;sup>10</sup> EPO, Board of Appeals, 12 March 2012, No. T 1553/06, Philips c/ DSM

<sup>&</sup>lt;sup>11</sup> See Exhibit 3: Affidavit from Ms. Martin, visitor of the 2017 Batomat Fair

Based on the above, it appears all features of claims 1 and 3 of the Patent have been disclosed by La Nuova Tessera prior to filing the Patent.

Further, nothing in the dependent claims 2 to 7 may confer novelty to such claims.

The Patent shall therefore be revoked for lack of novelty.

# 2.3 In any event, the absence of infringement of the Patent

**17.** Unlike what the Claimants argue, the sale of transparent covers to The Tuilerie by Bad-Glass cannot constitute indirect infringement as will be demonstrated below.

### 2.3.1 The transparent covers do not relate to an "essential element" of the invention

- 18. It shall be underlined that although they bear the burden of proof of the indirect infringement they invoke, the Claimants do not bother demonstrating how the transparent covers would relate to an essential element of the invention. In support of their claim, they simply offer a misleading presentation<sup>12</sup> of the Patent that tends to give the impression that the transparent cover (3) of the Patent is an essential element by omitting the real essential elements of the invention.<sup>13</sup>
- 19. In reality, the transparent cover cannot relate to an essential mean of the invention considering that it does not participate to the result of the invention. 14 Indeed:
  - even if the transparent cover (3) were omitted, the primary (alleged) technical teaching of the Patent would still hold, i.e. increasing the efficiency of the solar collector *via* heat dissipation through the combination of the metal plate and the fluid-tight passageway. Indeed, the transparent covers (3) do not have any functional interaction with the metal plate (7) and the fluid-tight passageway (9).<sup>15</sup>
  - 2. it was already known in the prior art to use transparent covers for photovoltaic tiles with high solar transmittance rate (see Figure 3 of the Patent). 16 Yet, it does not result from the description of the Patent that the transparent covers used in the invention would have a new function compared to the transparent covers used in prior art, which served to (i) admit solar radiation into the roof tile 17 and (ii) protect the solar collector from rain and dirt. 18
  - 3. the transparent cover (3) and its 91.0% solar transmittance **does not, in any case, contribute to the improved heat dissipation**. It is actually quite the opposite because the high amount of energy traversing the cover (3) will increase the amount of heat to be dissipated!
- **20.** Further, no claim of the Patent refers to the technical teaching of the transparent cover (low iron oxide content). This is a further sign that the transparent cover is technically secondary.

<sup>12 §8-10</sup> of the Statement of Claim dated 15 May 2024

<sup>13 [011]</sup> of the Patent

<sup>&</sup>lt;sup>14</sup> See *Paris Court of Appeals, 4 March 2009, No. 07/08437* which held that supply of means only constitutes an act of infringement if the means provided relate to an essential element of the invention, namely to participate in its result. See also

See BGH GRUR 2006, 570, 571, extracoronales Geschiebe which hold that a means relates to an essential element of the invention if it is capable of functionally interacting with one or more features of the patent claim so as to implement the protected invention. See also LG Düsseldorf, 4b O 108/03 – "Kaffeekapseln"., pt 132/133.

<sup>16</sup> See Dutch Supreme Court, Case C02/227HR, Sara Lee v Integro which held that the essential element must be the element that distinguishes the invention from the prior art.

<sup>17 [008]</sup> of the Patent

<sup>&</sup>lt;sup>18</sup> [008] of the Patent, last sentence

As shown above, the transparent cover does not contribute to the technical result disclosed in the Patent. Thus the transparent covers sold by the Defendant cannot constitute a means, relating to an essential element of the invention.

# 2.3.2 No knowledge that The Tuilerie uses the covers for solar panels according to the Patent

- 21. The Claimants try to demonstrate knowledge by Bad-Glass by referring to its website and the infringement action initiated before the Tribunal Judiciaire. 19
- 22. Yet, Bad-Glass website only shows a schematic drawing of a roof tile without any technical information as to the details of the solar panel: therefore, the roof tile that the transparent cover can be used with is not necessarily the one covered by the Patent. This can in no case constitute an inducement within the meaning of Article 26(2) UPCA.
- **23.** Further, as clearly mentioned by the same website, the glass covers may <u>also be used for windows</u>. <sup>20</sup> Given the multiple possible applications of the glass covers other than in the claimed device, the Defendant had no reason to suspect that The Tuilerie made roof tiles according to the Patent.
- **24.** Finally, the sole fact that a previous infringement action was launched is no evidence that the criteria of Article 26(2) UPCA are met, even more so as the previous action is still pending.

# Thus the knowledge criteria for indirect infringement is not met.

### 1.2.1 In any event, the exception provided by Article 26(2) of the UPCA applies

- **25.** A staple commercial product may be defined as one which is supplied commercially for different uses. As explained above, this is the precisely the case for glass covers sold by Bad-Glass.
- **26.** Further, there is no evidence that The Tuilerie manufactures roof tiles according to the Patent, and that Defendant induced The Tuilerie to manufacture roof tiles according to the Patent, so that the requirements of Article 26(2) UPCA are met.

Thus, all indirect infringement allegations raised by the Claimants shall be dismissed.

### 2.4 On the relief and remedies requested by the Claimants

#### 1.2.2 The permanent injunction request shall be dismissed

- **27.** Claimants argue that since Bad-Glass has infringed the Patent, the Court "will grant" their request for a permanent injunction.<sup>21</sup>
- 28. Yet, neither the UPCA, nor the Rules of Procedure of the UPC, allows for automatic injunction. It is quite the opposite since both set of rules are instilled with the principle of

<sup>19 §18</sup> Statement of Claim dated 15 May 2024

<sup>&</sup>lt;sup>20</sup> See Claimants' Exhibit No. 3

<sup>21 §19</sup> Statement of Claim dated 15 May 2024

proportionality and require that a balance of interests be made by the Court before ordering any injunction measures.<sup>22</sup>

- 29. This is not surprising considering that EU law is the primary source of law for the UPC. Yet, Article 3 of the Enforcement Directive requires the application of a proportionality test before granting injunctions and Article 12 provides for alternative measures of pecuniary compensation in lieu of an injunction when the person liable acted without negligence and if the injunction would cause disproportionate harm. Recent European case law has shown that courts indeed seek to strike a balance between patent rights and public interest when granting preliminary or permanent injunctive relief.<sup>23</sup>
- **30.** Hence, there is no doubt that the UPC shall assess the measures requested by the Claimants in light of the principle of proportionality and shall balance the interests of the parties involved, as well as of the general public, before granting an injunction.
- **31.** In this specific case, the requested injunction is clearly **disproportionate** as Bad-Glass products can be used in many applications and is not infringing any patent.
- **32.** Moreover, the products present strong advantages for the **environment and public health** and **for the consumers**.
- 33. Indeed, the transparent covers manufactured by Bad-Glass may be assembled with solar collector to obtain photovoltaic roof tiles other than the ones covered by the Patent. Such system helps reducing carbon dioxide (CO<sub>2</sub>) emissions, which is beneficial for the environment and hence for the public health.

Further, such system, as it enables homes and buildings to generate their own electricity and can even be used to heat water<sup>24</sup>, allows cutting down on gas and electricity spending, which is especially important for the whole society in the circumstances faced in Europe.

The only adequate measure for the future would therefore be a reasonable pecuniary compensation.

Considering that the transparent covers manufactured and sold by Bad-Glass can be used in many different applications and may contribute to the generation of cheap and green electricity, an injunction would negatively impact the public interest and hence shall be rejected.

#### 1.2.3 The request for provisional damages shall be dismissed

**34.** Assuming that Bad-Glass committed infringement acts, these were not committed knowingly, or with reasonable grounds to know as:

<sup>&</sup>lt;sup>22</sup> For example: Article 41(3) of the UPCA: "The Rules of Procedure [...] shall ensure <u>a fair balance</u> between the legitimate interests of all parties", Article 42 of the UPCA: "(1) The Court shall deal with litigation in ways which are <u>proportionate</u> to the importance and complexity thereof. (2) The Court shall ensure that the rules, procedures and remedies provided for in this Agreement and in the Statute are used in <u>a fair and equitable manner</u> and do not distort competition."Article 2 of the Rules of Procedure: "The Rules shall be applied and interpreted in accordance with Articles 41(3), 42 and 52(1) of the Agreement on the basis of the principles <u>of proportionality</u>, flexibility, fairness and equity." Article 3 of the Rules of Procedure: "3. Proportionality shall be ensured by giving due consideration to the nature and complexity of each action and its importance."

<sup>&</sup>lt;sup>23</sup> For example, taking into consideration public health; Paris Judicial Court, 3 June 2022, 22/52718, Novartis v. Biogaran, UK Patents Court, 24 May 2018, EWHC 1256, Edwards Lifesciences LLC v. Boston Scientific SCIMED INC, Court of Turin, 16 June 2021, 10009/2020, Edwards Lifesciences v. Meril Life Sciences and Viglia.

<sup>&</sup>lt;sup>24</sup> Solar tiles: Advantages, examples, and costs in the UK (selectra.com)

- Contrary to what the Claimants argue, the fact that the University had, prior to launching this action before the UPC, launched a patent infringement action before the Tribunal Judiciaire does not, in itself, imply that Bad-Glass knew it was infringing the Patent.
- This is especially true that Bad-Glass had, prior to launching their solar covers, as they do with all new products, requested an outside counsel legal opinion of their counsel on the risks of infringement of third parties' patents.<sup>25</sup> Such opinion comforted their view that their products would not be infringing any valid patent.
- **35.** In any event, the amount requested is unjustified and excessive. Indeed, Article 68(2) UPCA forbids punitive damages: only damages that place the injured party in the position it would have been if no infringement had taken place may be ordered.
- **36.** According to the Claimants, they should be awarded a lump sum of EUR 2,500,000, based on an alleged 5% rate reference in the field (not defined), and calculated on pure fanciful (and not evidenced) figures and numbers and on the erroneous assumption that all transparent covers have been used with roof tiles according to the invention.

Hence, neither the EUR 2,500,000 presented as final damages, nor the EUR 250,000 provisional damages are justified. Hence, the request for provisional damages shall be dismissed.

#### 1.2.4 The publicity measures shall be dismissed

**37.** The publicity requests raised by the Claimants do not appear justified nor proportionate to the issues at stake in the litigation and should be dismissed.

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### **PRAYERS FOR RELIEF**

The UPC is asked to:

- In principle, to STAY THE PROCEEDINGS initiated before the UPC by the Claimants'
  Statement of Claim dated 15 May 2024, until a final decision is issued in the French
  proceedings docketed under No. 23/00202; and DECLINE ITS JURIDICTION once the
  jurisdiction of the Tribunal Judiciaire is established.
- 2. In the **alternative**, to **REVOKE** patent EP2 305 607 B1 entirely, to **FIND** that Bad-Glass did not infringe EP2 305 607 B1, and to **DISMISS** all Claimants' requests for corrective or injunction measures.
- **3.** In **any case**, to order Claimants to **REIMBURSE** all legal and court fees incurred by Bad-Glass.

#### 3 LIST OF EXHIBITS

**Exhibit 1**: Promotional email sent by La Nuova Tessera to its clients

**Exhibit 2:** YouTube Video and related bailiff report

**Exhibit 3:** Affidavit from Ms. Martin, visitor of the 2017 Batomat Fair

Due to the privileged information it contains, this legal opinion will only be filed to the proceedings after appropriate confidentiality measures are taken pursuant to Rules 190, 262A, 287 and 292(2).

# DEFENCE TO THE COUNTERCLAIM FOR REVOCATION AND REPLY TO THE STATEMENT OF DEFENCE

# FOR:

- UNIVERSITÉ DES SCIENCES DE MARSEILLE établissement public à caractère scientifique, culturel et professionnel, registered under SIREN number 123 456 789, whose registered office is located avenue des Prix Nobels, in Marseille, France, represented by its President
- 2. **LA NUOVA TESSERA**, a company registered under the laws of Italy, whose registered office is located soleggiata strada piastrellata, in Tiramisu, Italy, represented by its CEO,

**CLAIMANTS** 

# Represented by:

# Jean-Hyacinthe de Mitry

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#### **Mathilde Rauline**

European Patent Attorney SANOFI 1883 rue de la convention de paris, 63000 Clermont-Ferrand (France) Mathilde.Rauline@for-themock.Auvergne

# **VERSUS**:

**BAD GLASS,** a company registered under the laws of Tiledavia, whose registered office is located 54, Imagination, 1227 Tiledavia

**DEFENDANT** 

#### Represented by:

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**Oliver Tischner** 

**LAVOIX** 

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L'ORÉAL

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#### **MAY IT PLEASE THE COURT**

(1) Further to the Defendant's statement of defence, the Claimants reply as follows

#### 1. REPLY ON THE STAY

(2) In the case ongoing before the Paris first instance court (*Tribunal Judiciaire*), initiated prior to the launch of this case before the Court, the University sued Bad-Glass for the infringement of the French part of the Patent and Bad-Glass, by way of defense, invoked the nullity of the same.

In its statement of defence of 15 July 2024, the Defendant requests that the Court stay this action pending the outcome of the French case, both on infringement and validity, based both on Articles 29 and 30 of Regulation (EU) No 1215/201.

# 1.1 The request for a stay on infringement

(3) The Claimants hereby renounces to their claims before the Court, with respect only to the infringement acts that are the subject-matter of the French case, namely the infringement of the French part of the Patent committed in France.

For the avoidance of doubt, the Claimants maintain their claims before the Court regarding the infringement acts of the Patent committed outside France.

As a consequence, the infringement action before the Court and the infringement action before the Paris first instance court have no longer the same subject-matter, since the action before the Court is now limited to Italy, Luxemburg, Cyprus and Portugal.

Therefore, there is no *lis pendens*, and article 29 of Regulation (EU) No 1215/2012 does not apply.

(4) Article 30 of Regulation (EU) No 1215/2012, which provides for the *possibility* for a court to stay proceedings if another court was seized prior to it of a related matter, also does not apply.

First, the judgment of the French supreme court of 28 June 2022 mentioned by the Defendant is not relevant since, in the case at hand, the matter brought to the Paris first instance court only relates to the infringement of the French part of the Patent, not to its Italian, Luxemburgish, Portuguese or Cyprian part.

Therefore, a stay would only lead to the unjustified suspension of an infringement case that does not relate to France.

Second, a stay would cause a considerable harm to the Claimants who currently suffer from the infringement of their Patent, due to acts notably occurring in Luxemburg.

Finally, even if the legislator has expressly envisaged a transitional period where, for a same EP patent, national courts and the Court have competing jurisdiction, and explicitly referred to Regulation (EU) No 1215/2012, applying broadly Article 30 of said regulation when national courts have been seized first may seriously harm the sovereignty of the Court and significantly jeopardize its utility.

Therefore, there is also no reason for the Court to order a stay on infringement based on Article 30 of Regulation (EU) No 1215/2012.

#### 1.2 The request for a stay on validity

(5) The Defendant has raised, by way of defence, the nullity of the French part of the Patent both before the Paris first instance court (*Tribunal Judiciaire*) and the Court.

However, since the Claimants have renounced to their claims before the Court with respect only to the infringement of the French part of the Patent committed in France, the Defendant has no standing to request, before the Court, the cancellation of the French part of the Patent.

This derives from Rule 25(1) which provides that "if the Statement of defence includes an assertion that the **patent alleged to be infringed** in invalid (...)."

Put it differently, a defendant to an infringement action can only invoke, by way of counterclaim, the nullity of a patent that is asserted against it. If this patent is not asserted against the defendant, it must file a nullity action if it desires to obtain its revocation.

In the case at hand, since the French part of the Patent is no more alleged to be infringed before the Court, the Defendant has no more standing to request its cancellation by way of counterclaim.

Consequently, the Defendant's request for a stay with respect to invalidity should be dismissed as well.

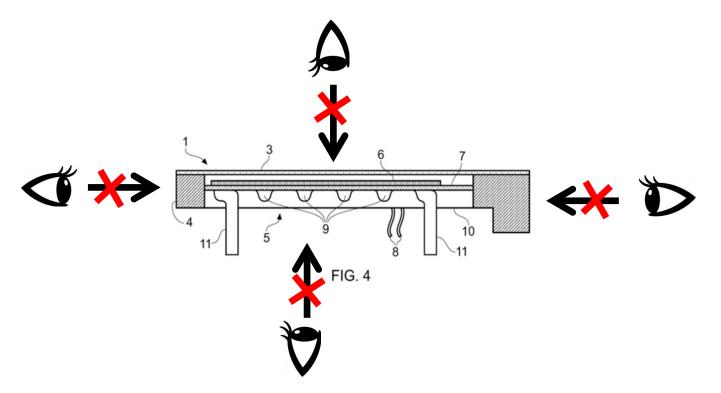
(6) In any event, if Article 30 of Regulation (EU) No 1215/2012 was to apply, the request for a stay should be denied as well for the same reasons at outlined above in 1.1, and notably the fact that it would paralyze the infringement claim outside France and therefore cause an irreparable harm to the Claimants.

#### 2. REPLY ON VALIDITY

#### 2.1 The granted invention

- (7) According to claim 1, the patent at issue concerns:
  - C1 a roof tile (1) comprising:
  - C2 a transparent cover (3) having a solar direct transmittance higher than 91.0%
  - C3 and a solar collector (5) wherein the solar collector (5) comprises
  - C4 a metal plate (7)
  - C5 and a fluid-tight passageway (9) for fluid
  - and wherein the metal plate (7) is arranged between the transparent cover (3) and the fluid-tight passageway (9) in such a way that heat can be transferred from the metal plate (7) to the fluid.
- (8) As described, the metal plate (7) ensures that heat is dissipated from the solar collector (5) (paragraph [010] in the patent specification) towards a fluid flowing through the fluid-tight passageway (9). The heated fluid exits the fluid-tight passageway (9) via a connector. This heated fluid can for example be used to heat a building (See paragraphs [010] and [013] in the patent specification).

(9) The roof tile (1) of the invention is illustrated notably in the figure 4 reproduced below:



(10) As can be seen, the fluid-tight passageway (9) is placed in a cavity defined by the metal plate (7) and a frame (4). This cavity is not opened anywhere.

As mentioned by the different bold crossed out arrows, it is not possible to observe the fluid-tight passageway (9) from anywhere when looking at the roof-tile.

# 2.2 Exhibits opposed by the Defendant

- (11) The Defendant opposes the following three items against the novelty of claim 1:
  - Exhibit Def. 1 : Promotional email sent by La Nuova Tessera;
  - Exhibit Def. 2: You Tube Video and related bailiff report; and
  - Exhibit Def. 3: Affidavit from Ms. Louise Martin, visitor of the 2017 Batomat Fair.
- (12) As preliminary matter, it is noted that in considering novelty, it is not permissible to combine separate items (EPO Guidelines for Examination G-VI-1).

Indeed, a document takes away the novelty of any claimed subject-matter derivable directly and unambiguously from that document. The limitation to subject-matter "derivable directly and unambiguously" from the document is important. Thus, when considering novelty, it is not correct to interpret the teaching of a document as embracing features which are not explicitly disclosed by this document (EPO Guidelines for Examination G-VI-2).

(13) In addition, it is a general principle that the more serious the issue the more convincing must be evidence be to support it.

If a decision on such an issue may result in refusal or revocation of a European Patent, for example, in case concerning alleged prior publication or prior use, the available evidence in relation to that issue must be very critically and strictly examined.

Before the EPO, a European patent should not be refused or revoked unless the grounds for refusal or revocation are fully and properly proved (See T 750/94, EPO OJ 1998, 32 and Case Law of the Boards of Appeal, 10<sup>th</sup> edition, III, G.4.3.1).

#### 2.2.1 Exhibit Def. 1

#### (a) Evidential value

(14) **Exhibit Def. 1** is a promotional email dated 25 September 2017, i.e. before the filing date of the patent at issue. This email has been sent by Ms. Laura Sorare.

Ms Sorare is the CEO of the La Nuova Tessera. She is a person of integrity, high quality and dedication to the company she founded.

(15) However, it appears from the e-mail that it was Ms. Sorare who printed **Exhibit Def. 1**, as her name is mentioned at the top left of the document.

It is inconceivable that Ms. Sorare would have forwarded a copy of this e-mail to the Defendant on her own initiative.

Thus, it is unclear how the Defendant obtained a copy of this e-mail previously printed by Ms. Sorare, and whether it obtained it through loyal and legal means.

(16) In addition, the e-mail was sent to a list of recipients, the scope of which is undefined.

Therefore, the public disclosure of the e-mail is not fully and properly proved beyond reasonable doubt.

- (17) For these reasons, **Exhibit Def. 1** should be dismissed by the Court or, at a minimum, considered to have a very low evidential value.
- (b) **Disclosure**
- (18) Exhibit Def. 1 reproduces Figure 1 and Figure 2 of the Patent at issue. However:
  - **Figure 1** shows part of a roof which comprises conventional roof and does not disclose the invention as claimed in claim 1.
  - Figure 2 is a perspective view of a roof tile according to the invention for an observer placed above the tile.

In this view, the inner part of the tile is not visible. The e-mail states that a flat fluid-tight passageway with circulating fluid is located behind the solar collector but there is no mention of the use of a metal plate and a specific interaction between this metal plate and the fluid tight passage.

(19) Thus, features C4 and C6 are not disclosed by **Exhibit Def. 1** and, consequently, claim 1 is novel over **Exhibit Def. 1**.

#### 2.2.2 Exhibit Def. 2

#### (a) Evidential value

(20) **Exhibit Def. 2** is a Youtube video presenting the functioning of a photovoltaic roof tile.

The content of this video before the filing date of the Patent at issue is not fully and properly proved. This video may have been modified during 2017.

For these reasons, **Exhibit Def. 2** should be dismissed by the Court or, at a minimum, considered to have a very low evidential value.

#### (b) **Disclosure**

(21) According to the Defendant, the CEO of La Nuova Tessera explains in this video that "the main advantage of their new tiles compared to prior art is that the new products allow heat dissipation thanks to the use of an ingenious system using the passing of fluid to cool down the whole system and present the prototype, showing the metal plate with flat fluid-tight passageways below the transparent cover" (statement of defence, page 5).

However, this video only shows combination of a roof tile comprising a transparent cover and a solar collector and does not discloses the fact that the transparent cover has a solar direct transmittance higher than 91.0%. Further the explanations about the internal features of the tile are vague, and not supported by an image.

(22) Thus, features C2 and C6 are not disclosed by **Exhibit Def. 2** and, claim 1 is novel over **Exhibit Def. 2**.

### 2.2.3 **Exhibit Def. 3**

- (a) Evidential value
- (23) **Exhibit Def. 3** is an affidavit from Ms. Martin, visitor of the 2017 Batomat Fair and describing the maquette exhibited at Batomat 2017.
- (24) This document raises the following remarks:
  - it is dated **18** July 2024 whereas it is quoted in a statement of defence filed on **15** July 2024. It is therefore obvious that it has been carefully prepared by the Defendant;
  - it is quite surprising that Ms. Martin has such a specific recollection of facts having occurred seven years prior to her affidavit, whereas she admits that she visits all booths at Batomat Fairs.

The fact that she was first explained "the context of the present proceedings" by the Defendant's representatives may be a reason for such fresh memories;

- finally, Ms. Martin mentions that she allegedly took pictures of the maquette. It is rather puzzling that such pictures are not attached to her affidavit.

This casts a serious doubt on the evidential value of this affidavit, which should be considered very low to say the least.

#### (b) **Disclosure**

- (25) The affidavit of Ms. Martin does anyway not mention the fact that:
  - the transparent cover has a solar direct transmittance higher than 91.0%,
  - the metal plate is arranged between the transparent cover and a fluid-tight passageway for fluid. As mentioned above, this could not be seen neither from looking at the tile.

Thus, features C2, C4, C5 and C6 are not disclosed by **Exhibit Def. 3** and, consequently, claim 1 is novel over **Exhibit Def. 3**.

- (26) This is in any event confirmed by the affidavit of Professor G. Montretou (exhibit 08), where he mentions that:
  - the maquette was protected by a dome of glass that the crowd or potential clients could see from 1 meter but could not touch. The dome of glass was never removed during the fair. It was anyway so fragile that nobody from La Nuova Tessera team could have moved it during the exhibition;
  - some prototypes of roof tiles according to the invention were also displayed under similar domes of glass, mounted as in a roof, therefore protected by rafters on their sides;
  - "nobody could see (i) that the plate below the glass was made in metal (ii) that there are some fluidetight passageway below this plate (iii) and even less how the heat can be transferred from the metal plate to the fluid"; and
  - Pr. Montretou was aware of the risks of disclosing the invention at the Batomat 2017 fair. Thus, He received a practical presentation from La Nuova Serra lawyers on how to avoid disclosing sensible information. He answered the questions he had, but mostly directed them to the maquette of a building with a roof tile according to the invention. The Professor is sure the invention was not disclosed during the fair.

\*

(27) As a result, it is established that Claim 1 is novel over the items invoked by the Defendant.

In any event, the defendant does not show that the features of dependant Claims 2 to 7 have been disclosed, meaning that if by extraordinary Claim 1 is revoked, Claims 2 to 7 will remain.

#### 3. REPLY ON INFRINGEMENT

- (28) The Defendant asserts that the transparent cover would not participate to the result of the invention and, therefore, would not be an essential means thereof (statement of defence, page 6), whereas:
  - although "the efficiency of photovoltaic modules decreases as their temperature increases" (paragraph [010]), the invention permits the absorption of such temperature in a system enabling, for instance, the heating of a building (paragraph [013]), meaning that a system according to the Patent requires a high temperature;

- according to the Patent (paragraph [016]), and to the Defendant, a transparent cover having a solar direct transmittance higher than 91% increases the amount of heat that enters the tile. Therefore, this transparent cover plays a key role in the heat transfer between the metal plate and the fluid passageway.

Put it differently, with a transparent cover having a low solar direct transmittance, generating therefore little heat, the Patent would be pointless.

Therefore, this transparent cover having a solar direct transmittance higher than 91% is an essential means of the Patent.

(29) The Defendant also asserts that La Tuilerie had no knowledge that it used the covers for solar panels according to the Patent (statement of defence, page 7).

This is irrelevant since the knowledge requirement of Article 26(1) UPCA applies to the "third party", who is the supplier of the essential means, not the user of the final product.

(30) The Defendant finally asserts that the exception of Article 26(2) UPCA would apply but it adduces no evidence that the disputed cover would be a staple commercial product.

\*

- (31) The Claimants maintain their claims as set out in their statement of claim, save that:
  - they withdraw their claims with respect only to the infringement of the French part of the Patent committed in France, which are the subject matter of the ongoing disputed before the Paris First Instance Court (*Tribunal judiciaire de Paris*); and
  - they request the Court to dismiss the request for a stay made by the Defendant in their statement of defence of 15 July 2024.

# SCHEDULE OF EXHIBITS

No.	Description
1	Patent EP 2 305 607
2	Purchase order of transparent covers from BadGlass by The Tuileries
3	Bad-Glass website, as appeared in March 2024 and still appears today
4	Analysis of a tile bought from The Tuilerie, comprising a transparent cover from Bad-Glass
5	Handbook of Düsseldorf Appeals Court Judge Kühnen
6	Opinion advocate general, MSD v Teva, 6 June 2017
7	Cass. com. 8-6-2017, n° 15-29.378 (7.1) and CA Paris, 4 March 2009 (2007/08437) (7.2)
8	Affidavit or Mr. Gaspard Montretou

Filed on 15 November 2024 Case No. 2024-0099

# **REJOINDER TO THE REPLY**

#### FOR:

**BAD-GLASS**, a company incorporated under the laws of the State of Tiledavia, Registration No. 2609567, having its head office at 54, Imagination road, 1227 Tiledavia, represented by its President,

Hereinafter the "Defendant"

# Represented by:

Pauline Debré	Oliver Tischner	François Rivière
Linklaters LLP	Lavoix	L'Oréal
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75008 PARIS	inventive – 75001	92300 LEVALLOIS-PERRET
pauline.debre@mock.com	PARIS	francois.riviere@mock.com
	otischner@mock.eu	

# **AGAINST:**

- (1) Université des Sciences de Marseille, établissement public à caractère scientifique, culturel et professionnel, registered under SIREN number 123 456 789, whose registered office is located at avenue des Prix Nobels, in Marseille, France, represented by its President.
- (2) La Nuova Tessera, a company registered under the laws of Italy, whose registered office is located at soleggiata strada piastrellata, in Tiramisu, Italy, represented by its CEO.

Hereinafter together the "Claimants"

# Represented by:

Jean-Hyacinthe de Mitry	Pierre-Yves Demaure	Mathilde Rauline
Gide Loyrette Nouel AARPI	ATOUT PI LAPLACE	SANOFI
1340 rue de l'Ordre des	1973 chemin de la CBE,	1883 rue de la Convention
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#### MAY IT PLEASE THE COURT

1. The Defendant maintains the arguments raised in its Statement of Defence and Counterclaim for Revocation, and replies as follows to the Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024.

#### 1 IN PRINCIPLE: THE PROCEEDINGS BEFORE THE UPC SHALL BE STAYED

- 2. The Defendant argued in its Statement of Defence that the proceedings before the UPC must be stayed pursuant to Article 29, and in any event under Article 30, of Brussels I Recast due to the existence of the prior French proceedings involving the same parties and the same cause of action.
- 3. In reply, the Claimants stated that they renounced before the Court their claims of infringements committed in France of the French part of the Patent. The Claimants therefore allege that as a consequence of this carve-out, neither Article 29, nor Article 30 of Brussels I Recast shall apply and that the request for the stay should be dismissed.<sup>1</sup>
  - The Claimants further argue that because of this carve-out, Bad-Glass would no longer have standing to request revocation of the French part of the Patent by way of counterclaim before this Court, so that the request for a stay should be dismissed in this respect.<sup>2</sup>
- 4. It will be shown below that the monolithic jurisdiction of the UPC prevents carving-out a territory from the scope of the claims, or a national part of the EP patent from a revocation action (1.1). Should the Court admit such carve-out, it would in any event stay the proceedings further to Article 30 of Brussels I recast (1.2). The question of standing, which has to be differentiated from the topic of the stay, will be dealt with in the next section.

#### 1.1 The carve-out request shall be dismissed

**5.** As a reminder, Article 34 of the UPCA enshrines the principle of the monolithic jurisdiction of the UPC:

#### Article 34

#### Territorial scope of decisions

Decisions of the Court shall cover, in the case of a European patent, the territory of those Contracting Member States for which the European patent has effect.

Pursuant to this Article, the decisions of the UPC – whether on infringement or nullity of an EP patent, shall cover, the territory of **ALL** contracting member states in which the EP patent is in force. Therefore, the parties do not have the possibility to request any other measure than one covering all member states in which the EP patent is in force.

- **6.** The option between the two routes UPC or national courts for EP patents during the transitional period was set only to allow the patent holders to stay with the EP system until they are confident that the new UPC system is performant. It was not aimed at creating a third route which would be a mix of the first two.
- 7. The reverse position, which would allow a territorial carve-out before the UPC, would be contrary to the spirit of the UPC which is aimed at improving the enforcement of patents by

Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, Section 1.1

Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, Section 1.2

limiting the number of actions that must be initiated, and at the same time, protecting the rights of the defendants by offering the possibility of a central revocation. A scenario where it would be possible for a patentee to protect a key market by first initiating an infringement action in such market, and then to later to file a UPC infringement action carving out such key market and hence protecting the national part of its EP patent of such market from the UPC jurisdiction and potential counterclaim for revocation, would be completely contradictory with the founding principles of the UPC. Moreover, allowing a carve-out would clearly contradict the rules of Brussels I Recast on *lis pendens*, e.g. in the presence of a revocation action covering the same title.

- 8. In addition, Article 34 UPCA would be either redundant or not make any sense, in case it was aimed at anything else than the scope of all the EP states of an EP patent.
- **9.** This is recognized by a majority of commentators:
  - "Article 34 UPC Agreement does not seem to allow for a territorially limited judgment"3;
  - "Territorial scope of decisions.

Decisions of the UPC cover the territory of those contracting member states where the patent is in force".4

• "The UPC provides a unified court for participating Member States instead of the existing patchwork of patent courts. There will be one decision for the entire UPC territory".5

# 1.2 In any event, should the carve-out be allowed, the UPC proceedings must be stayed

**10.** Pursuant to Articles 29 and 30 of Brussels I Recast, a court<sup>6</sup> must/can stay the proceedings brought before it where another court has been seized first of the same cause of action and between the same parties or of a related action with a risk of irreconcilable judgements.

For the purposes of this Article, actions are deemed to be related where they are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments resulting from separate proceedings.

The ECJ ruled in the Solvay v. Honeywell decision of 12 July 2012 that "a situation where two or more companies from different Member States, in proceedings pending before a court of one of those Member States, are each separately accused of committing an infringement of the same national part of a European patent which is in force in yet another Member State by virtue of their performance of reserved actions with regard to the same product, is capable of leading to 'irreconcilable judgments' resulting from separate proceedings as referred to in that provision".<sup>7</sup>

11. In this specific case, even if French acts were carved out, there is a risk of irreconcilable judgements considering that both actions relate to the same product, the same parties and the same alleged infringing acts. In the French proceedings, the alleged infringing acts

<sup>3</sup> Unified Patent Court: The Competent Court — Part II | All Alerts & Newsletters | Crowell & Moring LLP, See Exhibit No. 4

<sup>&</sup>lt;sup>4</sup> UPCAgreement.pdf (epo.org), see Exhibit No. 4

<sup>&</sup>lt;sup>5</sup> Jones Day, the Unitary patent and the Unified patent court, see Exhibit No. 4

<sup>6</sup> As a reminder, the UPC is treated as a court of a Member States for the purposes of Brussels I Recast (see Article 71(c)(2.) Brussels I recast).

<sup>&</sup>lt;sup>7</sup> ECJ, 12 July 2012, C-616/10 Solvay v. Honeywell

consist of presenting the transparent covers at a fair. In the UPC proceedings, it is of presenting the same products on the Defendant's website and offering them for sale, i.e "the two sides of the same coin".

Moreover, the Tribunal Judiciaire will be able to rule on the alleged infringement committed not only in France but also in the other jurisdictions where the Patent is in force and therefore could assess infringement in the same territories than the UPC.<sup>8</sup>

12. The Claimants argue that they would suffer from "irreparable harm" in the event of a stay, without substantiating such claim or establishing the existence of a prejudice. Should they have wished to obtain a decision quickly, they could have filed a request for preliminary injunction, which they did not do. In any event, the decision of the Tribunal Judiciaire will likely be issued in less than a year, and as recalled above the Tribunal Judiciaire will be able to issue a cross-border injunction if so requested.

The Court shall dismiss the carve-out request and, in any event, stay the proceedings until a final decision is issued in France.

#### 2 IN THE ALTERNATIVE, THE PATENT IS INVALID

**13.** Further to the argument set out in the Statement of Defence and Counterclaim for Revocation, Bad-Glass will show below that (2.1) it has standing to file a counterclaim for revocation for all territories covered by the Patent and that the Patent is invalid (2.2).

# 2.1 Bad-Glass has standing to request the revocation of the Patent in all territories

- 14. The Claimants argue that since they have renounced their infringement claims before the Court on the basis of the French part of the Patent, Bad-Glass would not have standing to request the revocation of the French part of the Patent.<sup>9</sup>
- 15. As detailed above, the carve-out shall be dismissed. In any event, nothing in the UPCA, nor in the Rules of procedure, specifies that a counterclaim for revocation shall or may be limited to the territories where an infringement is invoked. This, once again, shows that the UPC was conceived as having a monolithic jurisdiction and that no carve-out shall be accepted.
- **16.** Further, the UPCA does not make a distinction, when assessing standing to sue, between the conditions to file a main revocation action or a counterclaim for revocation action.
- 17. The question is then is it appropriate and of good administration of justice, if the carve-out is allowed, to rule on the validity of all national parts of the Patent knowing that a counterclaim for revocation is also pending before the Tribunal Judiciaire.
- 18. Bad-Glass admits that should the carve-out be allowed and the request for a stay denied, the UPC will then have to rule on the validity of the national parts of the Patent other than the French one. Indeed, if a carve-out for infringement is allowable, then for analogous reasons a carve-out for revocation must also be allowable.

Should the Defendant's request for a stay be denied, and the Claimants' request for the carve-out be denied, the Court shall rule on the counterclaim for revocation for all territories designated by the Patent.

<sup>&</sup>lt;sup>8</sup> French Supreme Court, 29 June 2022, No. 21-1.085

<sup>9</sup> Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, §5

Should the carve-out be allowed, and the stay denied, the Court shall rule on the counterclaim for revocation for all territories designated by the Patent, except for France.

#### 2.2 The Patent is invalid

19. The Claimants contest the counterclaim for revocation by disputing the evidentiary value of the exhibits provided and by challenging the novelty attack raised by the Defendant. The Court will see that the content and date of the novelty destroying disclosure are certain and will revoke the Patent (2.2.1).

In any event, the affidavit filed by the Claimants in support of their argumentation requires clarification during the hearing (2.2.2).

#### 2.2.1 Exhibit 5 discloses all the elements of claim 1 of the Patent

- 20. Pursuant to established case-law in the Member States and the EPO, for a disclosure to be novelty destroying, evidence is generally assessed in terms of what seems most probable.<sup>10</sup> Yet, as will be further detailed below, it appears highly probable that all technical features of claim 1 of the Patent were disclosed by La Nuova Tessera in the commercial email sent to its client in 2017, as later corroborated by the disclosures made during the Batomat fair. Using the applicable standard of proof, claim 1 and all dependent claims are not novel over public prior use.
- 21. Contrary to what the Claimants seem to argue, Bad-Glass does not combine several exhibits but relies on one email sent by Ms. Sorare, CEO of La Nueva Tessera, to all its clients on 25 September 2017 which discloses all features of claim 1 of the Patent. The other exhibits were filed only to corroborate this argumentation.
- 22. Short of arguments on the merits, the Claimants criticize the evidentiary value of the exhibit filed by Bad-Glass. Claimants insinuate that Bad-Glass would not have obtained **Exhibit 1** through loyal and legal means. This is obviously wrong and relies on purely speculation. In any event, a new Exhibit 5 containing the same email, as received and printed by Mr. Truth, client of La Nueva Tessera and contact of one of Bad-Glass's employees, is filed to these proceedings.<sup>11</sup>
- **23.** The Claimants admit that the email discloses all the features of claim 1 save the use of a metal plate.

Yet, this is not correct since the email contains a link to a YouTube video (Exhibit 2) in which the presence of metal plate is clearly mentioned and shown, and its interaction with the fluid-tight passageways is also explained.

Therefore, all the features of claim 1 were disclosed in this email.

**24.** Regarding **Exhibit 2**, Claimants further argue that the "content of this video before the filing date of the Patent at issue is not fully and property proved". 12

However, the date on which a video is published on YouTube appears below such video. A video on YouTube cannot be replaced by another without changing the URL link.<sup>13</sup>

<sup>10</sup> EPO Board of Appeals, 21 May 2014, T 0286/10, EPO Board of Appeals, 21 November 1994, T 0729/9

<sup>&</sup>lt;sup>11</sup> Exhibit No. 5: Promotional email dated 25 September 2017 as received by Mr. Truth

Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, §20

<sup>13</sup> Exhibit No. 6: Replace or delete your video - Computer - YouTube Help (google.com)

Yet, the screenshot inserted in the bailiff report filed shows that the video of Ms. Sorare was published on YouTube on 23 September 2017:<sup>14</sup>



Hence, there is no doubt that the video as filed is the same than the one uploaded on YouTube on 23 September 2017.<sup>15</sup>

25. To corroborate the disclosure, Bad-Glass filed the affidavit of Ms Martin (Exhibit 3). Again, Claimants start by raising artificial formal critics (long period between the event and the affidavit and briefing by outside counsels), which can all be similarly raised against the affidavit of Mr. Montretou.

The reproached lack of pictures attached to the affidavit of Ms. Martin was due to the fact that she had recently moved and was not able to find them in her new home. After hours of searching, she was finally able to locate them, so that an updated affidavit could be filed by Bad-Glass.<sup>16</sup>

It is clear from those pictures that the metal plate was visible, as admitted by Mr Montretou himself.<sup>17</sup>

26. The Claimants also state that the fluid-tight passageway (9) is placed in a cavity defined by the metal plate (7) and a frame (4) and that this cavity is not open anywhere. This is a simple allegation based on a misleading figure. The presence of a "frame 4" means that it is open on both sides and no opaque cover restricting view is suggested by the illustrations. Also, this item is disclosed at 1:00 to 1:30 of the video (Exhibit 2).

## 2.2.2 Mr. Montretou's affidavit suffers from several flaws – he should be heard in personal at the oral hearing

- 27. It results from his affidavit, 19 that Mr. Montretou was asked by the Claimants to comment on two very different things: (i) his memories of the 2017 Batomat fair and (ii) the video filed by Bad-Glass under Exhibit No. 2.
- **28.** The Court will form its own appreciation of the evidentiary value of Exhibit No. 2, so that the comments of Mr. Montretou in this respect do not have much use.
- **29.** The Court will also note that Mr. Montretou's recollection of Batomat 2017 suffers from several flaws.
  - First, Mr. Montretou explains in §6 that he had been prepped by La Nuova Tessera's lawyers prior to the fair in 2017 to avoid destroying disclosures. Yet, the very next

<sup>&</sup>lt;sup>14</sup> Exhibit No. 3: YouTube Video and related bailiff report, p.5

<sup>&</sup>lt;sup>15</sup> See EPO, Guidelines for Examination, Part G, 7.5.4, see also for example Paris Court of Appeals, 4 October 2019, No. 17/10062

<sup>&</sup>lt;sup>16</sup> Exhibit No. 3bis: Updated affidavit of Ms. Martin with pictures enclosed

<sup>&</sup>lt;sup>17</sup> Claimants' Exhibit No. 8, p.2

Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, §10

<sup>19</sup> Claimants' Exhibit No. 8

sentence of the affidavit mentions that the same lawyers explained to Mr. Montretou the context of the present proceedings. The sequence of these two sentences leads one to think that the preparation described did not actually take place before the fair but recently, in 2024, when the affidavit was prepared. One may therefore question the integrity of the affidavit.

- Second, it does not appear possible that Mr. Montretou spoke to 283 customers in a single day, especially given that he mentioned having in-depth discussion with around 100 individuals. Should these one-to-one talks have lasted around 5 minutes each (a minimum for an "in-depth" discussion), talking to 100 people would take 8 hours 33 minutes. Adding to this time other group discussions with circa 180 customers would result in a very long day way past the usual opening hours of a fair. This is a topical example of the approximations contained in the affidavit.
- Third, Mr. Montretou states that although visitors of the fair could see the metal plate, they would not have been able to identify the material of said plate, detail he did not disclose This is directly contradicted by Ms. Martin's affidavit.<sup>20</sup> Further, it results clearly from the video of Ms. Sorare and the pictures taken by Ms. Martin that the plate at stake presented metallic reflections, which in no doubt reveals the use of metal.
- 30. In view of the many approximations contained in his affidavit, Mr. Montretou shall be called as a witness and heard in person during the hearing scheduled on 21<sup>st</sup> November 2024 to confirm the content of the discussions he had with the visitors of Batomat 2017, and the exact layout of Nuova Tessera's booth. Considering Mr. Montretou can understand and write in English, he shall give evidence in this language.
- 31. In accordance with Rule 180(2) of the Rules of procedure, the Defendant is prepared to pay a sum that the Court will consider sufficient to cover the expenses incurred by the witness.

Based on the above, it appears all features of claim 1 of the Patent have been disclosed by La Nuova Tessera prior to filing the Patent. Further, nothing in the dependent claims 2 to 7 contribute novelty to such claims. The Patent shall therefore be revoked for lack of novelty.

In any event, Mr. Montretou shall be heard as witness in English during the hearing of 21<sup>st</sup> November 2024 to confirm the facts detailed in his affidavit.

#### 2 IN ANY EVENT, THE ABSENCE OF INFRINGEMENT OF THE PATENT

- **32.** The Claimants did not reply much on Bad-Glass arguments of non-infringement, which is not surprising considering that the accused transparent cover does not relate to an essential mean of the invention.
- **33.** The Claimants now try to argue that the photovoltaic tile "requires a high temperature"<sup>21</sup> and that with a low solar direct transmittance, "generating therefore little heat, the Patent would

<sup>&</sup>lt;sup>20</sup> Exhibit No. 3bis: Updated affidavit of Ms. Martin with pictures enclosed, §9: "I did not remember all details, but I remember that this was because of the way fluids could go through the module and cool down the **metal plate**, itself used to cool down the photovoltaic module."

<sup>&</sup>lt;sup>21</sup> Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, §28

be pointless".<sup>22</sup> If this were true, the Patent would be invalid for lack of disclosure considering that specified nowhere in the Patent it is that heat is needed.

This argumentation shows a misunderstanding of the technique of the alleged invention itself. Indeed, the photovoltaic technology does not rely on the absorption of heat, but of **light** (i.e. photons) from the sun. The technology works as follows: (i) photons hit the photovoltaic cells, (ii) the electrons then move around producing a direct electric current and (iii) this direct electric current is transformed into alternating current thanks to the inverters.

- Yet, light might reach the photovoltaic module even with a lower solar transmittance than 91% and therefore allows the production of energy. However, the more light that hits the module, the more such module will heat and such heat will be difficult to dissipate, thereby decreasing the efficiency of the whole device. The patented invention improves the dissipation and works without a transparent cover (100% direct solar light) and also with a transparent cover with a lower solar transmittance than 91%. Hence, the 91% value of solar transmittance is purely arbitrary and cannot be considered as relating to an essential element of the invention.
- **35.** As to the knowledge requirement of Article 26(2) UPCA, and as mentioned before, considering Bad-Glass also advertised its covers for use with windows, it had no reason to suspect that The Tuilerie made roof tiles according to the Patent.

Thus, all indirect infringement allegations raised by the Claimants shall be dismissed.

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#### **PRAYERS FOR RELIEF**

#### The UPC is asked to:

- 1. In **principle**, to **DIMISS** the carve-out requested by the Claimants and in any event, to **STAY THE PROCEEDINGS** initiated before the UPC by the Claimants' Statement of Claim dated 15 May 2024, until a final decision is issued in the French proceedings docketed under No. 23/00202; and **DECLINE ITS JURIDICTION** once the jurisdiction of the Tribunal Judiciaire is established.
- 2. In the **alternative**, should the stay be denied, to **SUMMON** Mr. Montretou to the oral hearing of 21st November 2021, to **REVOKE** Patent EP2 305 607 B1, to **FIND** that Bad-Glass did not infringe EP2 305 607 B1, and to **DISMISS** all Claimants' requests for corrective or injunction measures.
- 3. In any case, to order Claimants to REIMBURSE all legal and court fees incurred by Bad-Glass.

#### 3 LIST OF EXHIBITS

**Exhibit 1:** Promotional email sent by La Nuova Tessera to its clients

**Exhibit 2:** YouTube Video and related bailiff report

Exhibit 3bis: Updated affidavit of Ms. Martin with pictures enclosed

Exhibit 4: Doctrine on the jurisdiction of the UPC

Exhibit 5: Promotional email dated 25 September 2017 as received by Mr. Truth

Exhibit 6: Page "YouTube help"

Exhibit 7: Tile prototype [to be presented at the hearing]

Defence to the Counterclaim for Revocation and Reply to the Statement of Defence dated 15 September 2024, §28

E04D 13/18

F24S 20/69

(19)



### (12) EUROPEAN PATENT SPECIFICATION

(45) Date of publication and mention of the grant of the patent:

11.12.2019 Bulletin 2019/50

(21) Application number: 17123456.7

(22) Date of filing: 21.11.2017

(54) Roof tiles comprising solar collectors

Dachziegel mit Sonnenkollektoren

Tuiles de toit comprenant des capteurs solaires

(84) Designated Contracting States:

AT BE CH CY DE ES FR FI GB GR HR IS IT LI LU NL PT SE NO

(43) Date of publication of application:

26.6.2019 Bulletin 2019/26

(73) Proprietor:

(51) Int. Cl.:

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- La Nuova Tessera, Bergamo (IT)

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- Enzo Ferraro, Bergamo (IT)

(74) Representative:

Cabinet Bonne Mère IP, Marseille (FR)

Note: Within nine months of the publication of the mention of the grant of the European patent in the European Patent Bulletin, any person may give notice to the European Patent Office of opposition to that patent, in accordance with the Implementing Regulations. Notice of opposition shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European Patent Convention).

[001] The invention relates to roof tiles comprising solar collectors.

[002] Fig. 1 shows part of a roof which comprises conventional roof tiles 1. The roof tiles 1 are supported on roof battens 2. Adjacent roof tiles 1 interlock with each other. Conventional roof tiles may have different forms.

[003] A known solar collector of a first type provides electrical energy. It comprises a photovoltaic module which absorbs solar radiation and provides electrical energy. A known solar collector of a second type provides thermal energy. It comprises means for absorbing solar radiation to heat a fluid such as water or air.

[004] It is known to arrange solar collectors as solar panels. Typically solar panels are mounted on the roofs of buildings. Such solar panels disturb the appearance of the buildings. Furthermore they may become detached from the roofs in strong winds.

[005] An object of the present invention is to address these drawbacks. This is achieved by the subject matter of the claims.

[006] Brief description of the drawings: Fig. 1 shows part of a roof. Fig. 2 shows a roof tile according to the invention. Fig. 3 shows a cross section of a roof tile according to the prior art. Fig. 4 shows a cross section of a roof tile according to the invention. Fig. 5 shows a cross section of a roof tile according to a preferred embodiment of the invention. Figs. 6a and 6b show two alternative arrangements of a part of the roof tiles of Figs. 4 and 5.

[007] The invention will now be described with reference to the drawings.

[008] Fig. 2 shows a roof tile 1 according to the invention. It comprises a transparent cover 3 for admitting solar radiation into the roof tile 1, a frame 4 and a solar collector 5 for absorbing the solar radiation. The frame 4 supports the transparent cover 3 and holds the solar collector 5. The transparent cover 3 protects the solar collector 5 from rain and

dirt. The frame 4 can be made of ceramic and has the form of a conventional roof tile.

[009] Fig. 3 shows a roof tile 1 according to the prior art. The roof tile 1 comprises a transparent cover 3, a frame 4 and a solar collector 5. The solar collector 5 comprises a photovoltaic module 6, a metal plate 7 and electrical wires 8. The photovoltaic module 6 is mounted on the metal plate 7. The photovoltaic module 6 can absorb solar radiation and provide electrical energy via the electrical wires 8.

[010] The efficiency of photovoltaic modules decreases as their temperature increases. The metal plate 7 ensures that heat is dissipated from the photovoltaic module 6. The metal plate 7 is preferably made of a metal with a high thermal conductivity such as copper.

[011] Fig. 4 shows a roof tile 1 according to the invention. This roof tile 1 has improved heat dissipation. The roof tile 1 comprises a transparent cover 3, a frame 4 and a solar collector 5. The solar collector 5 comprises a photovoltaic module 6, a metal plate 7, electrical wires 8, a fluid-tight passageway 9 for fluid, connectors 11 for fluid and a thermal insulation layer 10. The fluid-tight passageway 9 follows a meandering path along the metal plate 7.

[012] The photovoltaic module 6 is mounted on the metal plate 7. The photovoltaic module 6 and the metal plate 7 are arranged between the fluid-tight passageway 9 and the transparent cover 3 in such a way that heat can be transferred from the metal plate 7 to the fluid.

[013] Fluid can enter the fluid-tight passageway 9 via one of the connectors 11. It then flows through the fluid-tight passageway 9 and exits the fluid-tight passageway via the other connector 11. The heated fluid can for example be used to heat a building. The fluid can for example be water or air.

[014] When mounting such roof tiles, the connectors of neighbouring roof tiles are interconnected via separate flexible hoses (not

shown), to form a solar collector system in which fluid can flow successively through a plurality of roof tiles.

[015] Fig. 5 shows a roof tile 1 according to an embodiment of the invention. A solar collector system comprising a plurality of these roof tiles can be quickly assembled. The roof tile 1 shown in Fig. 5 differs from the one of Fig. 4 only in the arrangement of the connectors. In the roof tile 1 of Fig. 5, the connectors are arranged as a plug connector 11a and a socket connector 11b. The plug connector 11a and socket connector 11b are so located on opposite sides of the roof tile, that when a plurality of such roof tiles are mounted as part of a roof, the plug connector of a roof tile engages with the socket connector of a neighbouring roof tile (not shown).

[016] Figs. 6a and 6b show two alternative arrangements of the fluid-tight passageways of the roof tiles shown in Figs. 4 and 5. In Fig. 6a, the fluid-tight passageway 9 is formed by a metal tube 12 having a circular cross section. The metal tube 12 is fixed to the underside of the metal plate 7, e.g. by soldering. In Fig. 6b, the fluid-tight passageway 9 is formed by the metal plate 7 and a metal wall 13 having a U-shaped cross section. The metal wall 13 is fixed to the underside of the metal plate 7, e.g. by soldering.

[017] In order to increase the amount of heat that enters the tile, the transparent cover (3) has a solar direct transmittance higher than 91.0%, preferably 91.5% or more. Such unusually high values can be obtained by reducing the amount of iron in the glass and by using chemical oxidizers such as antimony. Amounts lower than 0.010wt% of iron oxide are preferred.

[018] Roof tiles according to the invention can alternatively be made without photovoltaic modules and electrical wires. As in the roof tiles shown in Figs. 4 and 5, the metal plate of one of these roof tiles is also arranged between the fluid-tight passageway and the transparent cover in such a way that heat can be transferred from the metal plate to the fluid.

[019] A solar collector system can be formed from any combination of a plurality of roof tiles according to the invention.

#### Claims

- 1. A roof tile (1) comprising a transparent cover (3) having a solar direct transmittance higher than 91.0% and a solar collector (5), wherein the solar collector (5) comprises a metal plate (7) and a fluid-tight passageway (9) for fluid, and wherein the metal plate (7) is arranged between the transparent cover (3) and the fluid-tight passageway (9) in such a way that heat can be transferred from the metal plate (7) to the fluid.
- 2. A roof tile (1) according to claim 1, comprising a frame (4) which supports the transparent cover (3) and which holds the solar collector (5).
- 3. A roof tile (1) according to claim 1 or 2, wherein said solar collector (5) comprises a photovoltaic module (6) mounted on the metal plate (7).
- 4. A roof tile according to any preceding claim wherein the fluid-tight passageway (9) is formed by a metal tube (12) having a circular cross section or by the metal plate (7) and a metal wall (13) having a U-shaped cross section.
- 5. A roof tile (1) according to any preceding claim wherein the solar collector comprises a plug connector (11a) and a socket connector (11b) through which the fluid can enter and exit the passageway (9).
- 6. A roof tile (1) according to claim 5 wherein the plug connector (11a) and the socket connector (11b) are so located on opposite sides of the roof tile (1) that when a plurality of such roof tiles are mounted as part of a roof, the plug connector (11a) of a roof tile (1) engages with the socket connector (11b) of a neighbouring roof tile.
- 7. A solar collector system formed from any combination of a plurality of roof tiles (1) according to any of the above claims.

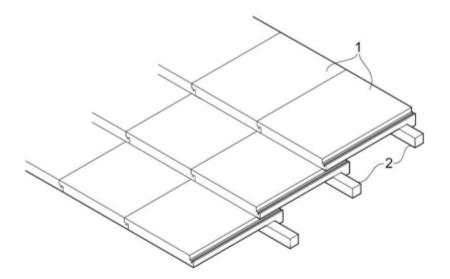


FIG. 1

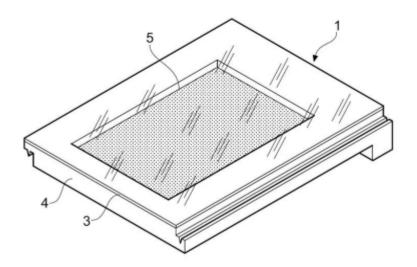


FIG. 2



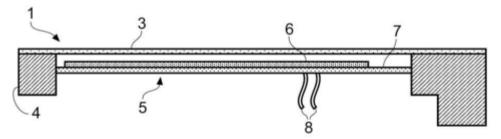


FIG. 3

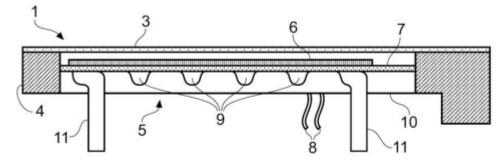


FIG. 4

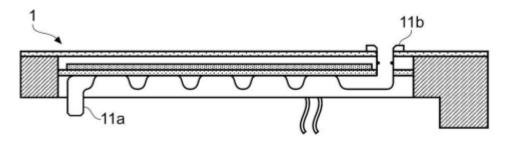
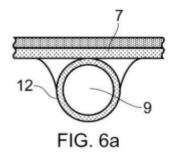


FIG. 5



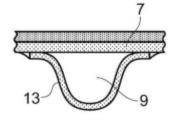


FIG. 6b

# **INVOICE**

DATE Nb# 04/01/2024 24025

**VENDOR** 

Bad Glass Penitentiary Road Conspiracy, 2004 Tileddavia

Phone: (261) 158 288 Fax: (261) 158 290

VATIN TLD4032013544513

#### **SHIP TO**

The Tuileries
Mufacture Avenue
Luxembourg, L-2090
Luxembourg
[Phone]

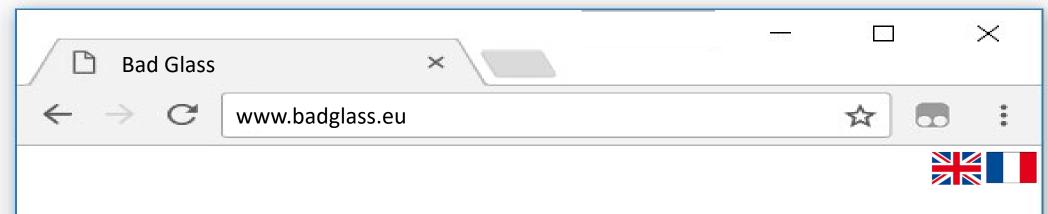
REQUISITIONER	SHIP VIA	F.O.B.	SHIPPING TERMS	
	Overland transport	Χ	general conditions of sale of Mar 2021	

ITEM#	DESCRIPTION	QTY	UNIT PRICE	TOTAL
SH69051000	Transparent covers "House-Bad" - size "roof tile"	15 m <sup>2</sup>	200,00	3 000,00
				-
				-
				-
				-
				-
				-
				-
				-
				-
				-
				-
				-
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				-
				-
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				-

#### **Comments or Special Instructions**

Please note that you ordered "House-Bad" transparent cover at "roof tile" size, but we can adapt to the size of other roof tiles if you have unusual tiles dimensions.

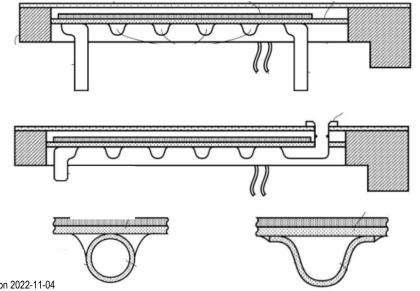
ΤΟΤΔΙ	FUR 3 000 00
OTHER	-
SHIPPING	-
TAX	-
SUBTOTAL	3 000,00



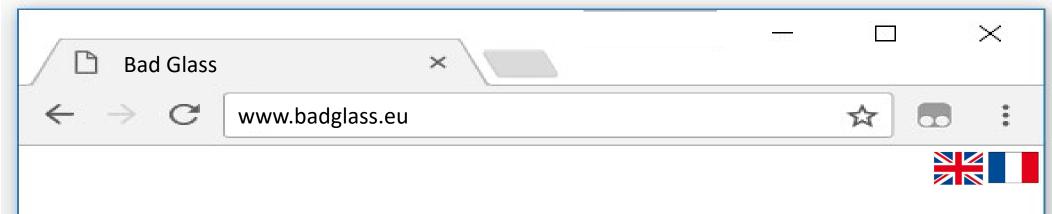
Bad-Glass provides you with ultra-performant transparent covers, called House-Bad®.

House-Bad® performance is linked with its incredible and innovative solar direct transmittance of 91.5%.

House-Bad® main use is on photovoltaic tile: we provide you with some technical drawings below. House-Bad® can also be used for others applications, such as windows.



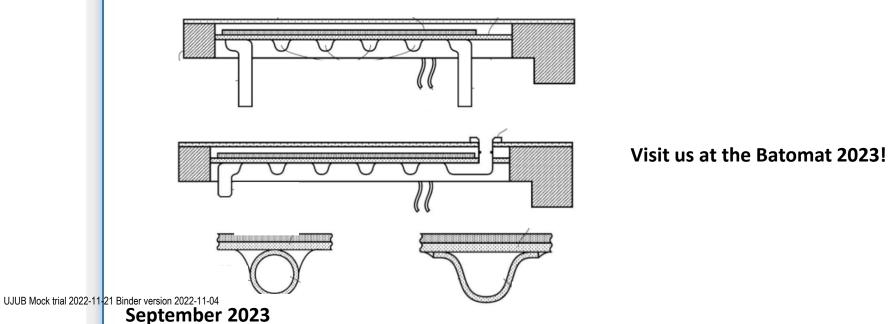
We are proud to announce that our transparent covers have now covered 1,000 buildings with photovoltaic tiles covered with House-Bad® !!



Bad-Glass provides you with ultra-performant transparent covers, called House-Bad®.

House-Bad® performance is linked with its incredible and innovative solar direct transmittance of 91.5%.

House-Bad® main use is on photovoltaic tile: we provide you with some technical drawings below. House-Bad® can also be used for others applications, such as windows.



# REPORT N°1789

<u>Commissioned by</u> : - **UNIVERSITÉ DES SCIENCES DE MARSEILLE** 

- LA NUOVA TESSERA

#### **INTRODUCTION**

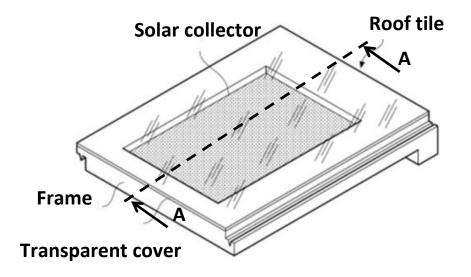
INDEPENDENCE LAB offers reverse engineering services that are characterised by including a thorough analysis of the examined part, in order to obtain as much information as possible about its geometry, quality of the material and manufacturing process.

These types of studies are valid for replicating discontinued parts, modifying designs, performing digital and virtual factory simulations, trouble-shooting related to patents, etc.

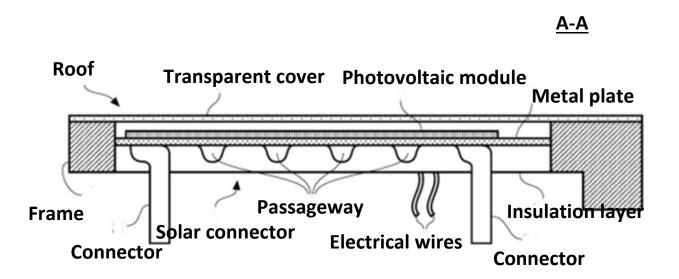
UNIVERSITÉ DES SCIENCES DE MARSEILLE and LA NUOVA TESSERA have commissioned INDEPENDENCE LAB to carry out a complete analysis of a tile, subsequently referred to as "tile bought from the Tuilerie".

INDEPENDENCE I A	
	F

**DESCRIPTION OF THE TILE BOUGHT FROM THE TUILERIE** 



Perspective view of the tile bought from the Tuilerie



Cross-sectional view of the tile bought from the Tuilerie according to A-A

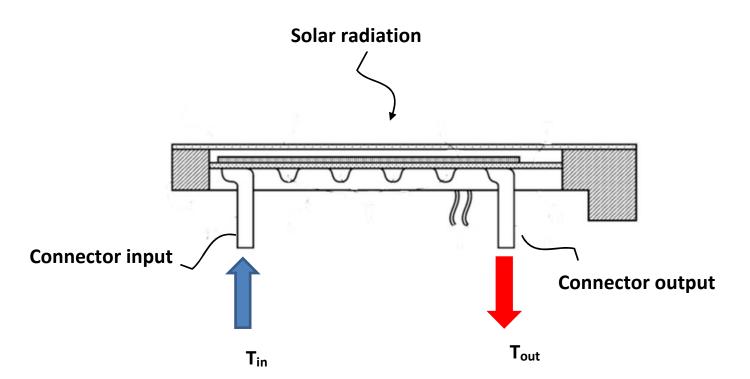
## **Feature A:**

"The metal plate is arranged in such a way that heat can be transferred from the metal plate to the fluid"

## **THE PROTOCOL**:

The test protocol is as follows:

- The tile is exposed to solar radiation during 2 hours.
- Water is injected via the connector input. The water velocity inside the tile is around 1,5 m/s.
- A the connector input, the water temperature is  $T_{in}$ .  $T_{in}$  is set to 15  $^{\circ}\text{C}$ .
- A the connector output, the temperature is  $T_{\text{out}}$ .  $T_{\text{out}}$  is measured by a common thermometer.



At the end of the 2 hours, T<sub>out</sub> has a value of 32 °C.

## **FEATURE B**:

"The transparent cover has a solar direct transmittance higher than 91.0%"

## **DEFINITION OF TRANSMITTANCE:**

The transmittance is a measure of the amount of light that passes through a transparent material. In other words, the transmittance is the ratio of the light passing through to the light incident on the transparent cover.

The standard test method for measuring transmittance is ASTM D1003-00 (Standard Test Method for Haze and Luminous Transmittance of Transparent Plastics, https://www.astm.org/d1003-21.html).

#### **TEST EQUIPMENT**

We use the instrument TT-W810 Light Transmittance and Haze Tester.



HOME / MATERIAL TESTING / PACKAGING TESTING

#### TT-W810 Light Transmittance and Haze Tester

Light transmission haze meter to test the light transmittance and haze degree of all transparent and semi-transparent parallel plane samples (plastic plate, sheets etc.), and turbidity or clarity of liquid samples (water, drinks etc.), used in the industries of plastics, membrane, coatings and paints, printing ink, research institute and so on.



Categories: Material Testing, Packaging Testing



#### **Light Transmittance and Haze Tester Standards:**

ASTM D1003-2007, JISK7105-81, GB/T 2410-2008

#### Light Transmittance and Haze Tester Specifications:

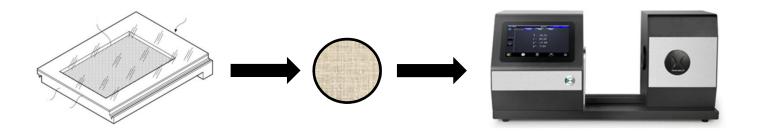
Item	Technical Parameters
Preheating time	30min
Accuracy	light transmittance: ≤1%haze degree: when haze degree≤0.5%, ≤±0.1%when haze degree > 0.5%, ≤±0.3%
Repeatability	light transmittance: 0.5% haze degree: when haze degree $\!\leq\!0.5\%$ , 0.05% when haze degree $\!>\!0.5\%$ , 0.1%
Test range	light transmittance:0~100.0%, haze degree: 0~30.0%
Minimum reading	light transmittance:0.01%, haze degree: 0.01%
Power supply	220v;60Hz
Weight	21kg

#### Light Transmittance and Haze Tester Instrument Structure:

Item	Technical Parameters
Optical system	Collimating lighting, diffuse horizon, integrating sphere photo electricity receiving method
Size of sample	Solid sample: 50mm×50mmLiquid sample: 50mm×50mm×10mmFilm sample: 50mm×50mm
Light source	Light source C (6774K)
Receiver	Silicon photocell
Electronic system	LCD
Size of sample window	Entrance window@25mm, exit window@21mm

## **THE PROTOCOL**:

- A test sample is generated. Typically, the test sample consists of a 50 mm diameter disc taken from the transparent cover.
- The test sample is inserted into the transmittance Tester.
- The value of the transmittance is measured.



The measured value of the transmittance is  $\underline{\textbf{91.5}\%}$ 

#### Translation of an excerpt of the handbook of Düsseldorf Appeals Court Judge Kühnen

As a rule, an element of the invention is already essential if it is part of the patent claim.<sup>647</sup> It does not matter whether the means in question (merely) appears in the generic term of the patent claim or whether it is mentioned in the characterizing part of the patent claim and thus distinguishes the subject matter of the invention from the prior art. 648 Likewise, it is sufficient if the means merely mentioned in general terms in the main claim is described in more detail in a back-referenced subclaim. 649 Therefore, the situation may arise that the offer and distribution of a subject matter that has been in use and in the public domain for a long time subsequently falls under the prohibition rights of Sec. 10 Patent Act because the subject matter in question is included in a combination patent. As a consequence, the previously unrestricted distribution can only be continued with the addition of a notice opposing the use of the combination in accordance with the patent. 650 It is also appropriate to demand such a notice from the offeror/supplier, because with the invention of the combination the possibilities of use (and thus the sales opportunities) of his product are increased and in view of this it is reasonable for him as the beneficiary to take precautions by means of appropriate notices to ensure that the use of his previously known product remains limited to the (previously served) public domain. Similar considerations apply if the means put on the market (e.g., a cell phone) has no relation to the subject matter of the invention at the time of its distribution, but as a result of its putting into operation, a functionality is assigned to it from the outside (e.g., by the default setting or a certain selected operating mode of the cell phone communication network), according to which the means makes a contribution to the invention.<sup>651</sup> Despite mention of the subject matter in the claim, the essentiality is exceptionally to be denied if the means in question does not contribute anything to the result of the performance according to the invention. 652

#### Practical tip

Example of wording

For the practical application of the law it follows: If the means offered or supplied, which is alleged to be indirectly infringing, is mentioned as such in the patent claim, it is usually an "essential element of the invention" simply because it is included in the claim of the patent. With this - simple - consideration, the vast majority of cases can be handled in practice. However, a "means relating to an essential element of the invention" need not necessarily itself realize a claim feature of the patent-in-suit. It is only decisive that, due to its design or due to its properties, it is capable of directly carrying out the invention in cooperation with other means. In this respect, it is sufficient if the use of the "means" (e.g., a DVD that is provided with video signals encoded in a certain way) leads to the patent-protected device (e.g., the receiving device of a DVD player for decoding the video signals) being used.<sup>653</sup>

Highlighted numbers respond to the following footnotes:

<sup>647</sup> BGH, GRUR 2007, 773 [BGH 27.02.2007 - X ZR 113/04] – Rohrschweißverfahren; BGH, GRUR 2015, 467 [BGH 03.02.2015 - X ZR 69/13] – Audiosignalcodierung.

<sup>648</sup> BGH, GRUR 2004, 758 [BGH 04.05.2004 - X ZR 48/03] - Flügelradzähler; BGH, GRUR 2007, 769 [BGH 27.02.2007 - X ZR 38/06] - Pipettensystem; BGH, GRUR 2015, 467 [BGH 03.02.2015 - X ZR 69/13] - Audiosignalcodierung. The case-law is in this regard not uniform in Europe, differently e.g. Hoge Raad de Nederlanden v 31.10.2003 in Bijblad Industriele Eigendommen 2004/47 - (Pilvormige) koffiebuiltjes voor de Senseo Crema.

- <sup>649</sup> OLG Karlsruhe, Urteil v 23.7.2014 6 U 89/13.
- <sup>650</sup> With regard to the existence of a positive use right from a patent with an older priority for the object as such, see Chapter E Margin no. 629 f.
- <sup>651</sup> A further question is whether the course of events in question is sufficiently foreseeable for the supplier of the means to meet the subjective requirements of contributory patent infringement. <sup>652</sup> BGH, GRUR 2007, 773 [BGH 27.02.2007 X ZR 113/04] Rohrschweißverfahren.
- <sup>653</sup> LG Düsseldorf, InstGE 7, 122 Videosignal-Codierung II. 654 BGH, GRUR 1990, 505 [BGH 21.11.1989 X ZR 29/88] Geschlitzte Abdeckfolie.

Conclusion
Case no: 15/04934
M.H. Wissink
Hearing: 9 June 2017
Opinion in the case of:
Merck Sharp & Dohme Corp.
formerly known as: Schering Corporation
(harainaftar: MSD)
(hereinafter: MSD)
v
1. Teva Pharma B.V.
2. Pharmachemie B.V.
(hereinafter jointly referred to as: Teva)
1Introduction
1.1
This case concerns the scope of protection of a second medical indication patent in the form of a

This case concerns the scope of protection of a second medical indication patent in the form of a subgroup patent with Swiss-type claims (purpose-bound process claims) and the question of when it is directly or indirectly infringed. The scope of protection of and infringement of second medical indication patents is still very unclear. These include the question of what meaning should be given to the 'manufacture' element (the process) in Swiss-type claims, the question of when there is direct infringement and the question - left open by HR 14 April 2017, ECLI:NL:HR:2017:692 (Sun/Novartis) - of whether indirect infringement of such a patent is possible.

#### 1.2

In its contested judgment, the Court of Appeal of The Hague focuses (not on the 'manufacture' element in Swiss-type claims, but) on the destination of the drug for the patented indication. In doing so, he distinguishes between the classic second medical indication (2M-I) patent for the invention that an already known substance is also suitable for the treatment of a condition other than the already known condition (as was at issue in Sun/Novartis), and a subgroup indication (SG-I) patent for an innovative method of treating a selection of patients from the group already treated with the substance. The EP 861 patent at issue is a subgroup patent for treatment with ribavirin for a selection of patients with chronic hepatitis C who were already being treated with it. The court aims to delineate the scope of protection of an SG-I patent in such a way that it does not include the pre-existing use of the substance for group treatment, but only its use for the subgroup defined in the SG-I patent. To this end, the court limits the scope of protection of an SG-I patent to the situation where it is specifically stated by a third party that the substance is intended for the subgroup. In my view, this general limitation is too restrictive.

#### 1.3

Although this could be the end of the matter, for the purposes of continuing the debate after cassation and reference, I make some additional observations.

In my view, the Supreme Court's case law on the interpretation of patents provides room for the recognition that the element of 'manufacture' in Swiss type claims rests on a fiction and therefore should not mean that the patentee is not entitled to protection in situations where such protection is justified. In my opinion, protection should be provided - via the doctrine of indirect infringement or, if one attributes significance to the element 'manufacture' via that of direct infringement - in the situation where the manufacturer/dealer of a generic medicine knows or can foresee with a sufficient degree of certainty that his medicine, notwithstanding a carve-out in the SmPC or package leaflet, will be used by third parties for the patented indication but fails to take adequate precautions to prevent such use.

I further believe that, contrary to the court of appeal's opinion, it does not follow from HR 31 October 2003, ECLI:NL:HR:2003:Al0346 (Senseo) as a general standard that a 'means relating to an essential element of the invention' as referred to in section 73(1) ROW (indirect infringement) constitutes that by which, according to the patent specification, the patent's teachings are distinguished from the prior art.

#### 2. Facts 1

#### 2.1

Chronic hepatitis C is a serious viral infectious disease. The condition, which is insidious and progressive, can result in liver cirrhosis, decompensated liver and/or hepacellular syndrome and requires treatment. Hepatitis C virus (HCV) occurs in several variants, designated genotypes 1 to 6.

#### 2.2

European patent EP 0 707 855 (hereinafter: Grint), published on 24 April 1996, discloses in the form of a Swiss-type claim the combination of ribavirin and interferon alpha for the treatment of, inter alia, naive chronic hepatitis C patients for the duration of 6 to 12 months, without differentiating by hepatitis virus genotype. 'Naive patients' refers to patients not previously treated.

#### 2.3.1

MSD2 is holder of European patent 0 956 861 (hereinafter EP 861 or the patent), which was granted to it on 24 April 2002 for, inter alia, the Netherlands on an application dated 13 May 1999, invoking priority since 15 May 1998 of US 79566. The description of EP 861 (hereinafter also referred to as the EP 861-Description) includes the following, in the uncontested Dutch translation:

'Background of the invention

(...)

Alpha interferon monotherapy is widely used for the treatment of chronic hepatitis C infections. (...). However, this monotherapeutic treatment was found to be ineffective. A combination of alpha-interferon and ribavirin was proposed (...). However, no one has described the methods with alpha interferon and ribavirin that destroy HCV RNA in the long term and are effective for anti-viral naive patients with genotype-specific HCV infection.

(...)

Summary of the invention

(...)

We found that if the antiviral treatment-naive patient has HCV genotype 1 infection, or if the antiviral treatment-naive patient has HVC genotype 1 infection and has a viral load of more than 2 million HCV-RNA per ml, as determined by quantitative PCR, that the application of combination therapy is carried out for a duration of 40-50 weeks, preferably 48 weeks.

(...)'.

#### 2.3.2

Conclusion 1 of EP 861 as granted reads in the - insofar as relevant: undisputed - Dutch translation as follows:

'The use of ribavirin for the preparation of a pharmaceutical composition for the treatment of a patient with chronic hepatitis C infection, for destroying detectable HCV-RNA, where the pharmaceutical composition serves to administer an active amount of ribavirin, together with an active amount of alpha-interferon, characterised thereby that the ribavirin, together with the alpha-interferon, is for administration over a period of time of about 40-50 weeks, where the patient is a patient naïve to anti-viral treatment with HCV genotype 1 infection and a viral load of more than 2 million copies per ml of serum, as determined by HCV-RNA quantitative PCR. '

#### 2.3.3

Claim 2 assumes the use of interferon for the preparation of the pharmaceutical composition mentioned in Claim 1, while Claim 3 assumes ribavirin and interferon together for that purpose. EP 861's claims, like Grint's, are Swiss-type claims.

#### 2.4.1

EP 861 was upheld unchanged after opposition before opposition division of the European Patent Office (EPO) and (twice) appeal in opposition before the Technical Board of Appeal (TKvB) of the EPO.

#### 2.4.2

In paragraph 35 of its first decision, that of 25 October 2006 (T 1399/04), the TKvB addressed the objectors' appeal to Grint (= OD8). First, it considered the following in relation to this document:

'Document (OD8) (...) discloses the usb of ribavirin, interferon alpha or both on the manufacture of a pharmaceutical composition for treating chronic HCV infections (claims 1 to 3). The patients may be previously untreated, thus antiviral treatment naïve (column 3, line 36), and the duration of the treatment is from 6 to 12 months (claim 11).

The document does not refer to a specific HCV genotype and does not mention the virus load of the patients.'

On EP 8613, paragraph 35 considers the following:

'(...) The patent in suit does not refer to numerical values or ranges but to the treatment of a specific sub-group of human patients within all human beings suffering from HCV infection'

(...)

If the use of a compound was known in the treatment or diagnosis of a disease of a particular group of subjects, the treatment or diagnosis of the same disease with the same compound could nevertheless represent a novel therapeutic or diagnostic application, provided that it is carried out on a new group of subjects which is distinguished from the former by its physiological or pathological status (cf. decisions T 19/86 (...) and (...) T 893/90).

The patient group according to present claims 1 to 3 is defined as being infected by a specific genotype of HCV, genotype 1, which is a pathological characteristic allowing to differentiate members of this group from all other HCV patients, and it is further defined by a viral load of greater than 2 million copies per ml of serium, which is a physiologically characterising feature. Both features are not disclosed in document (OD8).

According to the established case law of the Boards of appeal, cf decisions T 19/86 and T 893/90 (supra), the subject-matter of claims 1 to 3 represents a new therapeutic application as the patient group concerned is distinguishable from the patient group of document (OD8) by its physiological and pathological status.'

#### 2.5

MSD markets capsules and tablets pursuant to EP 861 under the brand names 'Rebetol' and 'Copegus' respectively.

#### 2.6.1

Pursuant to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (hereinafter: RI 2001/83), the placing on the market in the Member States of medicinal products for human use requires an authorisation (Article 6). Under Article 8, the application for it must be accompanied, among other things, by the test results of clinical and pre-clinical trials (paragraph 3(i)) and a summary of product characteristics (hereinafter SmPC, short for Summary of Product Characteristics). Article 10 provides that, by way of derogation from Article 8(3)(i), the applicant is not required to submit clinical and pre-clinical tests if he can demonstrate that the medicinal product is generic in relation to a reference medicinal product already authorised. Article 11 prescribes what data must be included in the SmPC, and in what order. In this case, the following sections listed therein are relevant:

- 4.1 = Therapeutic indications;
- 4.2 = Dosage and route of administration;

- 4.3 = Contraindications;
- 4.4 = Special warnings and precautions for use;
- 5.1 = Pharmacodynamic properties.
2.6.2
Article 11 further contains the following passage:
'For authorisations under Article 10, those parts of the summary of product characteristics (the SmPC, A-G addition) of the reference medicinal product that refer to the indications or dosage forms, which were still covered by patent law at the time a generic medicine was marketed, need not be included.'
On this footing, when parts of the SmPC of the reference medicine are omitted from the SmPC of a generic medicine, this is referred to as a carve-out. A SmPC of a generic drug provided with carve-outs is also referred to as a 'skinny label'.
2.7
Teva B.V. was granted - with Rebetol and Copegus as reference medicines - two market authorisations for the marketing of generic ribavirin through the central European registration procedure in 2009, viz:
- for capsules on 31 March 2009 ('Ribavirin Teva', marketing authorisation EU 1/09/509), modified on 16 November 2009 via a 'Type II variation';
- for tablets on 19 October 2009 ('Ribavirin Teva Pharma B.V.', marketing authorisation EU 1/09/527), updated on 22 January 2010 via a 'Type II variation'.
2.8
Pharmachemie is designated in the SmPCs and package leaflets of Teva B.V.'s generic ribavirin as 'Manufacturer' and 'Manufacturer responsible for release' of Ribavirin Teva and Ribavirin Teva Pharma B.V. in the European Union.

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2.9.1
Sections 4.1 and 4.2 of the SmPC accompanying the amended marketing authorisations for Teva's capsules state the following:
'4.1 Therapeutic indications
()
Patients not previously treated
Adult patients: Ribavirin is indicated, in combination with interferon-alpha-2b, for the treatment of previously untreated adult patients with all types of chronic hepatitis C except genotype 1 ()
Children and adolescents: Ribavirin is intended for use, in combination with interferon-alpha-2b, for the treatment of previously untreated children and adolescents aged 3 years and older with all types of chronic hepatitis C except genotype 1 ().
()
Patients who did not respond to previous treatment
Adult patients: Ribavirin is indicated, in combination with interferon-alpha-2b, for the treatment of adult patients with chronic hepatitis who have previously responded to monotherapy with interferon-alpha () but who subsequently experienced a relapse.
4.2
Dosage and route of administration
().

Based on the results of clinical trials, it is recommended that patients be treated for at least six months.

Ribavirin capsules in combination with interferon-alpha-2b:

(...)

Duration of treatment - not previously treated patients

Other than genotype 1: the decision to continue treatment for up to one year in patients with negative HCV RNA after six months of treatment should be based on other prognostic factors (e.g. Age ' 40 years, male gender, septal fibrosis)

Duration of treatment - repeated treatment

Genotype 1: treatment should be continued for a further six-month period (i.e. a total of one year) in patients who have shown a negative HCV-RNA after six months of treatment.

Other than genotype 1: The decision to continue treatment for up to one year in patients with negative HCV-RNA after six months of treatment should be based on other prognostic factors (...).'

#### 2.9.2

The passages underlined (by the court) refer to indications or dosage forms that qualify as 'carved out'.

#### 2.9.3

Sections 4.3 and 4.4 of the aforementioned SmPC do not warn against adverse reactions and urge caution when handling the capsules for the category of naive patients with HCV4 genotype 1 who are 'carved-out' in sections 4.1 and 4.2. Section 5.1 of that SmPC describes, among other things, three clinical trials involving combinations of ribavirin and interferon-alpha-2b in naive patients infected with all genotypes of HCV. About one of these studies, C/198-580, the following was stated in section 5.1:

'In this study, the combination of ribavirin and peginterferon-alpha-2b (...) was significantly more effective than the combination of ribavirin and interferon-alpha-2b, especially in patients with genotype 1 infection.'

This includes a table breaking down the results in genotype 1 by viral loads of more and less than 600,000 IU/ml, among others.

#### 2.9.4

The sections/passages reproduced above from the SmPC for Teva's capsules are identical in content to the corresponding sections/passages in the SmPC for Teva's tablets.

#### 2.10

Paragraph 1 of the package leaflet for Teva's generic ribavirin tablets according to the amended marketing authorisation states:

'Ribavirin Teva Pharma B.V. is used in adults in combination with peginterferon alfa-2b or interferon alfa-2b, for the treatment of patients with chronic hepatitis C. The situations in which Ribavirin Teva Pharma B.V. can be used in adults are shown below:

'In combination with interferon alfa-2b or peginterferon alfa-2b in adults not previously treated for chronic hepatitis C (...).'

The package leaflet for the generic Teva capsules does not differ substantially from that for the tablets.

#### 2.11

Teva introduced its generic ribavirin tablets to the Dutch market in June or October 2011. It does not and has not marketed ribavirin capsules in the Netherlands.

#### 3Proceedings

#### 3.1

By summons of 11 December 2009, MSD claimed in the counterclaim - prior to the introduction of the generic ribavirin tablets on the Dutch market - a declaratory judgment that Teva's generic products fall within the scope of protection of EP 861, with, for the territory of the Netherlands, a prohibition of infringement and various ancillary claims, as well as an order to pay damages or to pay profits, to be made up in state, costs pursuant to Section 1019h Rv.

In the counterclaim, Teva sought a declaratory judgment of non-infringement and, subject to the condition that infringement was accepted, the annulment of EP 861, claiming that the patent was not subsequent, new or inventive, for which it claimed costs pursuant to Section 1019h of the Dutch Code of Civil Procedure.

#### 3.2

By judgment of 10 November 2010, the District Court of The Hague dismissed MSD's claims and upheld Teva's counterclaim for a declaration of non-infringement.5 MSD was ordered to pay the costs of the proceedings in the claim and counterclaim on Teva's side, estimated at a total of €160,000.

The Court first of all noted that MSD, when asked, expressly did not plead that Teva would be performing reserved actions at that time and that there were no legally valid indications for the position taken by MSD that Teva was threatening to do so (paragraph 4.2). The Court then considered that MSD had confirmed in oral argument that the only ground on which it based its claims that Teva would come under the scope of protection of EP 861 were the market authorisations (paragraph 4.3). According to the court, Teva has adequately ensured by means of a so-called "carve-out" that it remains outside the scope of protection of the Swiss-type use claims of the patent and the current SmPC (with "carve-out") should be looked at to find out the destination of the ribavirin known by itself (para 4.4). The court considered that Teva had rightly argued that its generic ribavirin did not meet the technical characteristics a.) naive patients and b.) known with HCV genotype 1 according to the indications and dosage instructions, and thus already fell outside the scope of protection of the patent's Swiss-type claims, which relate to a very specifically circumscribed patient group, which is specifically excluded in Teva's SmPC (paragraph 4.6).

#### 3.3

MSD lodged an appeal against the judgment of 10 November 2010 with the Court of Appeal of The Hague. On appeal, MSD also invoked indirect patent infringement and tort, consisting of inducing, promoting, profiting from and inciting patent infringement. MSD amended its claims accordingly at the MoU.

#### 3.4

By judgment of 14 July 20156 - by which time the generic ribavirin tablets had meanwhile been introduced on the Dutch market - the Court of Appeal of The Hague upheld the District Court's judgment and dismissed MSD's claims on appeal, ordering MSD to pay the costs of the appeal proceedings on Teva's side estimated at €120,000. To this end, the Court of Appeal considered, inter alia:

"3.2 Schering's argument on appeal can be represented as follows.

A. Doctors - who at the time of the infringement have knowledge of the treatment protocol describing the application patented with EP 861 - will understand from (in particular section 5.1 of) Teva's SmPCs and package leaflets that Teva's generic ribavirin can be used for that application (i.e. for the treatment of naive patients with a genotype 1 infection). They will therefore prescribe that generic drug for this patient group, or at least it is very likely ('inherently probable'), while some pharmacists will also dispense that drug for that purpose and some patients will use it for that

purpose (e.g. paragraphs 4.14, 4.20, 4.23-4.28, 4.34, 4.35, 4.47, 4.48 and 4.52 MoU; paragraphs 13-16 PA).

B. The totality of information contained in Teva's SmPCs and package leaflets describe all patented features, and thus the patented application, so that Teva commits direct patent infringement (para 4.21 PA).

C. In any case, indirect patent infringement occurs now that:

- (i) offering and supplying generic ribavirin on the basis of the SmPC and package leaflet qualifies as offering and supplying means relating to an essential element of the invention, and
- (ii) Teva knows, or at least it must be clear to it in the circumstances, that the drugs (its generic Ribavirin) are suitable and intended for the application of the invention described in section A above (paragraphs 4.22 et seq. MoU; paragraphs 18 and 19 PA),

taking into account that doctors, pharmacists and patients acting as described under A do not apply the prior art/Grint, but the patented invention (para 4.52 MoU).

D. There is, even if the package leaflet were to describe the prior art, incitement to infringement because the description in the leaflet leads to or encourages the patented application.

(...)

Scope of protection; general observations

#### 4.1

Teva has taken the position that EP 861 selects a small group of patients from a large group that was already treated with the combination of ribavirin and interferon alpha in the prior art and that EP 861 rests solely on the finding that (a) naive patients with (b) genotype 1 infection and (c) a high viral load can benefit from (d) 40-50 weeks of treatment. The court follows Teva in this position which is consistent with the patent claims, the passages of the EP 861 Description reproduced in paragraph 1.3, and also the passages of the TKvB decision reproduced in paragraph 1.4.

4.2

The claims of EP 861 are designed as Swiss-type claims that were deemed necessary under the 'old' European Patent Convention (EPC) - in connection with Article 53(c) thereof - to patent a new therapeutic use of a substance for which a therapeutic use was already known. Such a new therapeutic use could include the following cases:

- the substance is used in a disease (the 'new' disease) other than the disease in which it was used in the prior art, the classic second medical indication (hereinafter: 2M-I);
- the substance is applied as in EP 861 to a subgroup of the group to which the known indication was already applied, hereinafter: the subgroup indication (in short: SG-I).

Teva rightly emphasised (paragraphs 30 and 74 MoA and paragraph 20 PA) that there is a substantial difference between these two categories of inventions. In a 2M-I invention, the substance is used for an indication for which it was not previously used, and the invention lies in this new use. In an SG-I invention, the substance is used for an indication for which it was previously used, and the invention lies in identifying the subgroup, in this selection. This difference has consequences for the scope of protection of the patent (which here includes the acts reserved to the patentee), see also the passage in the Protocol on the Interpretation of Article 69 of the EPC, which states that the interpretation of a patent is partly determined by the 'reasonable' protection due to the patentee, thus expressing that the protection of the patentee should not go beyond what is justified by his invention.

## 4.3

A 2M-I patent protects against the use of the substance to treat the 'new' disease. If a substance is marketed by a third party without specifically disclosing this 'new' use, but also without any (serious) restriction regarding the use, the substance marketed by that third party may also be used for the treatment of the 'new' disease, and thus the benefits of the patent are realised by someone other than the patent holder. Therefore, the scope of protection of a 2M-I patent can extend to commercialisation of the substance by a third party, even if it does not specifically state that it is intended for the 'new' use. This idea underlies the judgment delivered by this court on 27 January 2015 in the 'Novartis/Sun' case (case no. 200,150,713/01; IEF 14599; BIE 2015, no. 15, p. 79).

## 4.4

An SG-I patent protects against the use of the substance for the selected subset of patients. If this substance is marketed by a third party without specifically mentioning this 'new' use, but also without placing any restriction on the use, then it may be that that substance is also used for the treatment of the subgroup, but - unlike in the case of a 2M-I patent - this does not mean that the benefits of the patented are realised by someone other than the patent holder. After all, it was already known in the prior art to use the substance for the group of patients to which the subgroup belongs so that that substance could also be used to treat that subgroup. To realise the benefits of an SG-I invention, it is therefore necessary for the substance to be used specifically for the subgroup

(and in this case, moreover, for a specific treatment duration). This entails that - as Teva has argued in, inter alia, paragraph 21 PA - the scope of protection of an SG-I patent is limited to the situation where it is specifically stated by the third party that the substance is intended for the subgroup (and in this case also for the specific treatment duration).

4.5

It follows from what has just been considered that the case law focused on the characteristics of 2M-I patents lacks relevance in this case. Schering's argument based thereon (see, inter alia, paragraphs 9, 19 and 20 PA) is therefore disregarded.

Direct infringement

5.1

The court will now first assume presumptively that there is a direct infringement situation here, for example because the scope of protection of a Swiss-type claim - which concerns a process - extends to the directly obtained product under Article 64 (2) EPC (...).

5.2

As a result of the considerations set out in paragraph 4.4 in fine, in this case direct infringement requires in any case that the average person skilled in the art will believe, on the basis of the SmPC and/or the leaflet accompanying Teva's generic ribavirin, that it is specifically intended for the subgroup referred to in paragraph 4.1 (in short: the Genotype 1 naïve subgroup, abbreviated: G1N subgroup), as argued by Teva in inter alia paragraphs 21, 24 and 38 PA. (...)

5.5

The considerations under 5.3 and 5.4 entail that the minimum requirement for direct infringement referred to in paragraph 5.2 has not been met. For this reason alone, Schering's reliance thereon cannot succeed.

Indirect infringement

6.1

The Court of Appeal will now presuppose that this is an indirect infringement situation.

6.2

Indirect infringement is regulated in Article 73 of the IP Convention, which - like, for instance, its German and English counterparts - is derived from Article 26 of the 1989 Community Patent Convention (CPC), which never entered into force (...).

6.3

The concept of 'essential element'/'essential constituent'/'wesentliches Element' is not limited to an element that is in itself new and inventive, see Benyamini, p. 199 and, inter alia, the decision of the Bundesgerichtshof (BGH) of 4 May 2004, X ZR 48/03 BGHZ 159, 76, in which it was considered under 2.c):

'Insbesondere ist es nicht möglich, die wesentlichen Elemente einer Erfindung danach zu bestimmen, ob sie den Gegenstand des Patentanspruchs vom Stand der Technik unterscheiden.'

6.4

What matters, however, is whether 'means'/'resources'/'Mittel' ('relating to an essential element of that invention, for putting it into effect therein') are offered or supplied by Teva. (...)

In its judgment of 31 October 2003 on coffee pods (Sara Lee/Integro), ECLI: NL:HR:2003:Al0346, the HR expressed that a means relating to an essential element of the invention as referred to in Article 73(1) ROW constitutes that by which, according to the patent specification, the doctrine of the patent is distinguished from the prior art.

6.5

It follows from the above under 4.4 in fine, 5.3 and 5.4 that the generic ribavirin offered and supplied by Teva:

(...)

- starting from the coffee pads judgment of the HR: does not constitute that which, according to the patent specification (cf. paragraph 4.1), distinguishes EP 861 from the prior art.

With Teva (inter alia paragraphs 89-90 MoA and paragraphs 72-76 PA), it must therefore be concluded that, in the circumstances of this case, generic ribavirin is not a 'means' within the meaning of Section 73 ROW concerning an essential element of the invention of EP 861. Schering's claim of indirect infringement is already barred on this ground.

## Resume and conclusion

## 7.1

Summing up the foregoing, there is - based on the grounds mentioned in rel. 1.9 and 1.10 - there is no direct or indirect patent infringement by Teva, regardless of whether Teva's generic ribavirin is prescribed, sold and supplied by doctors and pharmacists, respectively, for the application patented in EP 861 (treatment of the G1N subgroup) and regardless of whether that drug is used by naive genotype 1 patients. Schering's relevant contentions (see paragraph 3.2 at A) therefore lack relevance.

# 7.2

Schering's assertion, in the context of its ground 6, that - contrary to the District Court's opinion - Teva's SmPCs and leaflets from the period before the amendments to the marketing authorisations referred to in paragraph 1.7 (i.e. from the period before 22 January 2010), which are not provided with carve-outs, are still relevant, does not hold water. In that period, Teva did not yet market its generic ribavirin in the Netherlands, while there is no reason to assume that Teva would use those 'old' SmPCs and package leaflets again. Because Teva's ribavirin did not come on the market in the Netherlands until well after 22 January 2010 (namely in June or October 2011), it cannot be assumed, as Schering still argued in this regard, that the 'old' SmPCs and package leaflets influenced the knowledge of the public and thus the prescribing behaviour of doctors.

# 7.3

Schering has not based its reliance on tortious act sec. on any facts other than its reliance on direct and indirect patent infringement. Taking also into consideration that in particular the figure of indirect patent infringement is essentially a substantiation of the general doctrine of tort in situations such as the present ('Patentgefährdung'), there is no room to rule differently on the tort claim than on the patent infringement claims.

# 7.4

Schering's offer to prove that doctors and pharmacists apply the invention of EP 861 by prescribing Teva's ribavirin and/or patients by using it (see paragraphs 4.34 and 5.1 MoU) is irrelevant in the light of the considerations under 7.1 to 7.3 above and is passed over on that ground.

# 7.5

In conclusion, Schering's claims are not allowable, not even on the new grounds and in the form put forward for them on appeal, and the declaration of non-infringement claimed by Teva is allowable. The court therefore correctly ruled in this sense. Its decision in rel. 2.2 at (a), (b) and (d) are correct and sufficient for its decisions. Schering's grievances fail. As the unsuccessful party on appeal, it will be ordered to pay the ensuing Section 1019h Rv costs assessed at the sum of €120,000 agreed by the parties for that purpose."

#### 3.5

MSD lodged a timely appeal in cassation, by summons of 13 October 2015, against the judgment of 14 July 2015. Teva moved to dismiss the cassation appeal. On 30 September 2016, oral argument took place at MSD's request, on which date MSD also submitted a written explanation (MSD s.t.) in addition to its written pleading. Teva has indicated that its written pleading also serves as a written explanation (hereinafter: Teva's pleading).7 After the oral pleading, where the parties had the opportunity to present oral reply and rejoinder, the parties, with the permission of the President of the Chamber, subsequently also submitted written rejoinders (hereinafter: MSD's reply) and duplicates (hereinafter: Teva's rejoinder).

# 4Discussion of the appeal in cassation

#### 4.1

In essence, the plea disputes the fact that the scope of protection of a subgroup patent is limited to the situation in which a third party specifically indicates that the substance is intended for the subgroup (parts 1.1-1.7) and the consequences that the court of appeal attaches to this for the assessment of whether there is a direct infringement (parts 2.1-2.6) and an indirect infringement, the latter partly in view of the court of appeal's interpretation of section 73 ROW 1995 (parts 3.1-3.13). Furthermore, the plea contains related complaints about the rejection of MSD's offer of proof (subsections 4.1-4.2), the dismissal of the claim in tort (subsections 5.1-5.3) and a general complaint (subsection 6.1).

## 4.2

Before discussing the plea complaints, I make some introductory remarks on second medical indication patents in the form of Swiss-type claims and on the discussion of the scope of protection of and infringement of such patents. The judgment under appeal should be read against this background.

## Second medical indication patents

# 4.3.1

The invention that a (already known) substance has a therapeutic application may be eligible for a patent (a first medical indication patent). The invention that this substance is also suitable for a (new) therapeutic application other than the already known application may also be eligible for patent protection.8 This is referred to as a second medical indication patent.9

## 4.3.2

Within the group of second medical indication patents, a further distinction can again be made between what the court calls classic second medical indication (2M-I) patents and subgroup

indication (SG-I) patents. The classic second medical indication patent concerns the invention that the substance is also suitable for the treatment of another ('new') condition.

In subgroup indication, although the substance is used to treat an already known condition, it is used in a way that is innovative in one or more respects. The innovation may be in the identification of a subgroup of the patient population and/or a dosing regimen, a treatment duration, a method of administration of the drug, etc.10

## 4.4.1

MSD points out the usefulness, costs and risks of 'new use' (i.e. 2M-I and SG-I) research and notes that patent applications are often made at a relatively early stage of drug development without actually bringing a drug to market all the time (s.t. nos. 2-8). Teva believes that for SG-I the term 'specific use' is more accurate, points to the importance of availability of (cheaper) generic drugs and draws attention to the phenomenon of 'evergreening', i.e. the stretching of monopolies on medical substances by continuing to apply for patents on all kinds of aspects where it is highly questionable whether there is any contribution to the state of the art (rejoinder nos. 2.1-2.5).

## 4.4.2

In all cases, a second medical indication patent will only be granted if (in the opinion of the granting authority) the invention meets, inter alia, the requirements of novelty and inventive step. In the case of an SG-I patent, the lay person might consider that the novelty and inventive step is problematic because the drug is already being used for the condition in question. However, the average person skilled in the art might judge that the technical doctrine of the patent adds (important) knowledge about the cases where the drug can be used more successfully. Since the therapeutic effect of the drug was already known before treating the group of patients with the disease in question, according to the TKvB, the designation of the subgroup will have to meet certain requirements if it is to be eligible for a separate patent. In particular, it requires that the subgroup be distinct from the patient group in pathological and physiological terms.11

# 4.4.3

With regard to EP 861, there was a 'novelty' debate and the TKvB held that the subgroup referred to in EP 861 was pathologically and physiologically distinct from the patient group referred to in Grint (see paragraph 1.4 of the judgment under appeal). In these proceedings, too, the parties argue about the extent to which EP 861 has advanced the state of the art (see in cassation MSD s.t. nos. 41 and 56 and pleading ch. 3; Teva pleading no. 2.11 and rejoinder nos. 2.11-2.12). However, because the District Court and the Court of Appeal did not get around to dealing with Teva's (conditional counterclaim for invalidity) (see paragraph 3.3 of the judgment), the starting point in cassation should be that EP 861 is valid. In assessing the plea, therefore, it must be assumed that the identification of subgroup (and treatment duration) 12 in EP 861 is (inter alia) novel and inventive.

Second medical indication patents in the form of Swiss-type claims

#### 4.5.1

Second medical indication patents were originally designed as purpose-bound process claims13 ("the use of substance X to manufacture a medicinal product for the treatment of disease Z"), so-called Swiss-type claims. The Swiss-type claim was conceived, and approved in 1984 by the Grand Board of Appeal of the European Patent Office (hereinafter: GKB),14 to make it possible to protect second medical indications as patents. Indeed, protecting second medical indications came up against the novelty requirement and the prohibition on patentability of therapeutic treatments. To avoid this, the aforementioned wording was devised as a working method claim.15

#### 4.5.2

With the revision of the European Patent Convention (hereinafter: EPC) in 200016, Article 54(5) EPC (and Article 4(6) ROW 1995)17 expressly provided that second medical indication patents were allowed.18 The CPC subsequently considered in a decision of 19 February 2010, G2/08, that this had removed the justification for the (wording of the) Swiss-type claim ("the loophole existing in the provisions of the EPC 1973 was closed")19 and ruled that the use of Swiss-type claims for European patent applications filed after 29 January 2011 was no longer allowed. From that date, second medical indications must be claimed by means of a purpose-bound product claim (hereinafter: EPC 2000 claim). Old Swiss-type claims, as at issue in this case, however, retain their effect according to the CPC decision.20

Scope of protection and infringement - general

# 4.6

Through interpretation of the patent, its scope of protection must be determined. Regarding the interpretation and thus the determination of the scope of protection of a patent, most recently21 HR 5 February 2016 (Bayer/Sandoz) considered:22

"3.3.4 Art. 69(1) European Patent Convention (EPC) implies that the scope of protection of a patent is determined by the claims of the patent document, with the description and drawings serving to explain those claims. Articles 1 and 2 of the Explanatory Protocol to Article 69 EPC (hereinafter: the Protocol) read, in Dutch translation:

"Article 1 - General principles

Article 69 should not be interpreted in the sense that the scope of protection of the European patent is determined by the literal text of the claims and that the description and drawings serve only to eliminate ambiguities which may exist in the claims. Nor should it be interpreted as meaning that the claims serve only as a guideline and that the protection extends also to what, in the opinion of the

expert examining the description and drawings, the proprietor of the patent has sought to protect. Instead, the interpretation must straddle these two extremes, providing both reasonable protection to the applicant and reasonable legal certainty to third parties.

## Article 2 - Equivalents

In order to determine the scope of protection conferred by a European patent, appropriate account shall be taken of any element equivalent to an element defined in the claims."

## 3.3.5

In line with this rule of interpretation of the Protocol, the Supreme Court has labelled the phrases used in its earlier decisions, "that which is essential to the invention the protection of which is claimed", respectively "the inventive idea lying behind the words of those claims", as a point of view, as opposed to the literal text of the claims (the "extremes" in the words of the Protocol) (cf. HR 7 September 2007, ECLI:NL:HR:2007:BA3522, NJ 2007/466 and HR 25 May 2012, ECLI:NL:HR:2012:BV3680, NJ 2013/68). Thereby, finding out the invention idea behind the words of the claims serves to avoid an interpretation based solely on the literal meaning of the words and therefore perhaps too limited or unnecessarily broad for a reasonable protection of the patentee (cf. HR 13 January 1995, ECLI:NL:HR:1995:ZC1609, NJ 1995/391). The description and drawings are an important source in that context. Part of the description is a representation of the prior art that the applicant considers useful for understanding the invention (Rule 42 of the Implementing Regulations to the EPC). Prior art not mentioned in the description may also be important. After all, when interpreting a patent, the perspective of the average person skilled in the art with his knowledge of the prior art is leading. (HR 4 April 2014, ECLI:HR:2014:816, NJ 2015/11 (Medinol/Abbott)).

(...)

# 3.3.8 (...)

Determining the scope of protection of a patent involves determining what the patent adds to the prior art. Only in the context of the infringement question can significance also be attached to the knowledge of the average person skilled in the art at the time of the alleged infringement, in particular as to whether there are equivalent elements (HR 4 April 2014, ECLI:HR:2014:816, NJ 2015/11 (Medinol/Abbott), para 3.5.2)."

Here, any patent must be interpreted in the context of the circumstances specific to that patent.23

#### 4.7

If a third party's product or process falls within the scope of protection of a patent,24 it then remains to consider whether the patent is infringed (directly or indirectly) by that third party.25

#### 4.8.1

Direct infringement occurs (subject to exceptions) if a third party performs one of the acts reserved in section 53(1) ROW 1995:26

- "1 A patent shall, subject to the provisions of Articles 53a to 60 inclusive, give the patentee the exclusive right:
- (a.) to manufacture, use, put into circulation or further sell, lease, deliver or otherwise deal in the patented product in or for his business, or to offer, import or stock the patented product for one or another;
- b.) applying the patented process in or for his business or using, marketing or further selling, renting out, delivering or otherwise dealing in the patented process in or for his business or offering, importing or stocking the product obtained directly from the application of that process."

Art 70(1) ROW 1995 further provides that the patent holder can enforce his patent against anyone who, without being entitled to do so, performs one of the acts mentioned in article 53(1).

## 4.8.2

Direct infringement requires that the third party himself (actively) performs the acts reserved to the patent holder. A manufacturer or trader who offers his product for the patented indication thus (in principle) commits direct infringement.

# 4.9

Even if a third party does not directly (directly) infringe, it is conceivable that he contributes to the fact that others do (or will be able to) do so and thus indirectly infringes the patent.27 Effective enforcement of the patent right then entails, that the patent holder can tackle the 'source' to prevent further infringements. Indirect infringement is regulated in section 73(1) ROW 1995:28

"The patent owner may institute the actions available to him in the enforcement of his patent against any person, who in the Netherlands, Curaçao or Sint Maarten, in or for his business, supplies means relating to an essential element of the invention to others than those who by virtue of Articles 55 to 60 inclusive are authorised to use the patented invention, offers or provides such means for the use of the patented invention in the Netherlands, Curaçao or Sint Maarten, provided that such person knows or it is clear in view of the circumstances that such means are suitable and intended for such use."

In HR 14 April 2017 (Sun v Novartis)29 the Supreme Court ruled on the science requirement in Section 73(1) ROW 1995. In the present case, the court ruled on the presence of a means concerning an essential element of the invention.

Scope of protection and infringement - second medical indication patents

outline of the problem

#### 4.10

Once the patent for the first medical indication has expired, the use of the substance for that medical application is free. That freedom concerns anyone who will use the substance for the previously patented application. This includes the whole chain including manufacturers, distributors and medical professionals. In practice, however, it is mainly the freedom of the producer and trader that is at stake, because enforcement of patent rights (also for practical and commercial reasons) is in principle not directed against medical professionals.30 The freedom to use the substance for the previously patented application means that producers and traders of generic products can enter the market and offer their generic medicine for that purpose, as far as patent law is concerned. However, if there is a second medical indication patent, the 'generic' has to respect it. Producing and marketing his generic medicine is then allowed under patent law, except for the protected second medical indication.

## 4.11

Thus, in this situation, on the one hand, the production and marketing of the generic product should be free as far as the now no longer patent-protected medical application of the substance is concerned and, on the other hand, the still protected application of the substance should be spared. Offering too much protection to the holder of the second medical indication patent unfairly hinders the market for the free uses of the product, offering too little protection unfairly denies the patent holder the reward for his contribution to the prior art. Finding this balance is complicated by the fact that, in the market for medicines, the manufacturer/dealer does not have complete control over which application its medicine is used for, and further by the question of how to determine the scope of protection of, and by extension an infringement of, a second medical indication patent.

# 4.12.1

Regarding the market for medicines, the following should be noted. The marketing of a medicinal product requires an authorisation. Every medicine has a Summary of Product Characteristics (hereinafter SmPC) and package leaflet. The manufacturer/dealer who states in the SmPC/insert of his generic medicine that it can (also) be used for the patented second medical application, runs the risk of thereby directly infringing the patent.31 To try to avoid this risk, the manufacturer/dealer may request the Medicines Evaluation Board (hereinafter: CBG) to remove the patented indication from

the SmPC and the product's package leaflet.32 Such a removal is called a carve-out and the relevant practice skinny labelling. The MEB's policy is to implement the carve-out only in the paper package leaflet and SmPC and to publish a full label version (i.e. without carve-out) on the MEB's website.33 Therefore, the information that is not included in the paper version is still publicly available on the MEB's website.34 Incidentally, this MEB policy is under pressure.35

## 4.12.2

Furthermore, the prescribing policy of doctors in the Netherlands36 means that in principle prescriptions are made by substance name, which encourages pharmacists to supply the cheaper generic product.37 In addition, a doctor's prescription - from a privacy point of view - does not state the indication/disorder for which the substance is prescribed. Therefore, the pharmacist cannot decide to dispense the drug of the holder of the second medical indication patent on the basis of the indication either. Pharmacists are also subject to guidelines that encourage them to dispense a generic drug when a branded product has been prescribed (the substitution policy).38 Furthermore, the health insurer may pursue a (contracting) policy of only reimbursing certain generic drugs in principle.39

#### 4.12.3

The above may result in the fact that if the manufacturer/dealer of the substance has included a carve-out in its SmPC and package leaflet, even if, considered in isolation, it sufficiently prevents reference to the use of the drug for the protected second medical indication, the generic drug is nevertheless used further down the chain for that indication.

does a carve-out suffice?

## 4.13.1

With second medical indication patents - or at least, according to paragraphs 4.3-4.4 of the currently contested judgment, with 2M-I patents - the question then arises whether the generic manufacturer/dealer, by having a carve-out included in the SmPC/insert, has done enough with a view to the interests of the patent holder, or whether its responsibility extends further if it is sufficiently established that its generic product is used or is likely to be used further down the chain for the patented indication.40

# 4.13.2

In his opinion (subsections 2.22-2.23) in the Sun/Novartis case, A-G Van Peursem referred to the growing consensus in the AIPPI context that a carve-out is not simply sufficient. A working group of the Dutch group of AIPPI concluded in 2014 that a carve-out does not necessarily entail that the science requirement is not met and there can be no (indirect) infringement. Resolution Q238 adopted by AIPPI on 17 September 2014 at the World Intellectual Property Congress in Toronto shows that it is also believed at the global level that skinny labelling does not necessarily entail that

there cannot be (indirect) infringement. According to this resolution, the (indirect) infringement question should always be assessed according to the circumstances of the case. For citations to these documents, I refer to the conclusion in Sun/Novartis.41 I also note that while the said resolution indicates a desirable direction, it notes that there are differences between legal systems on this point.42

## 4.13.3

In my view, the Supreme Court's judgment in Sun v Novartis also indicates that a carve-out is not straightforwardly sufficient. In the SmPC and package leaflet of its generic zoledronic acid, Sun had included a carve-out for the indication osteoporosis, which was covered by Novartis' second medical indication (2M-I) patent. HR 14 April 2017, ECLI:NL:HR:2017:692 considered:

"3.5.1 Part 2 opposes, with complaints of motivation, rulings 4.33-4.35 (and 4. 41, which refer back to it), insofar as the court of appeal ruled therein that Sun, in view of the preference policy applied by VGZ, was obliged to take effective measures to prevent the patent from being infringed further down the distribution channel, as well as that it had failed in its obligation to do everything possible to prevent its product from being supplied for the treatment of osteoporosis and to make sure that effective measures would be taken to that end. It is complained that the court does not make clear what measures it has in mind, nor how Sun, failing which, itself indirectly infringes the patent. Further, that the court did not take into account the impossibilities mentioned by Sun, while it cannot be seen that it can be held liable for the conduct of third parties over which it has no control.

# 3.5.2

The Court of Appeal held, uncontested in cassation, that it was virtually impossible that Sun's product would not also be supplied and used for osteoporosis and that it should therefore have known that its product would also be supplied for the patented indication at the end of the vertical marketing chain. The court correctly held that - assuming that indirect infringement of a [read] 'Swiss-type claim' is legally possible - the requirements of indirect patent infringement as referred to in section 73(1) ROW 1995 were met under those circumstances. The court of appeal did not rule that Sun can be held liable for the conduct of third parties over which it has no influence, so that the section to that extent cannot lead to cassation in the absence of a factual basis. According to the Court of Appeal, the reproach that can be made against Sun is that it did not do anything - except for the "carve-out" mentioned above in 3.1 under (viii) and the sending of the e-mail to wholesalers and hospital pharmacies, mentioned in paragraph 4.35, which the Court of Appeal (understandably) deemed insufficient - to prevent its product from being supplied for the treatment of osteoporosis (paragraph 4.34). It is not for the court to point out measures that a litigant such as Sun should have taken in a case such as the present, but, on the contrary, for the litigant itself to show what it has done to prevent infringement, notwithstanding the fact that the court of appeal in this case (in paragraphs 4.35 and 4.36) has given examples of conceivable measures. The impossibilities alleged by Sun to prevent the use of its product for the treatment of osteoporosis were not disregarded by the court of appeal. The court of appeal only charged Sun with having made insufficient use of the possibilities that were available to it.

The section therefore misses the point." (emphasis added; A-G)

It should be noted (i) that in this judgment the Supreme Court expressly did not answer the question of whether indirect infringement of a Swiss-type claim is possible or not (paragraph 3.3 under a) and (ii) the judgment refers to the knowledge requirement of section 73 ROW 1995 and not to the plea concerning an essential element requirement. Furthermore, this case in cassation did not concern a possible direct infringement.

## 4.14

Thus, although the question whether a carve-out is sufficient under Dutch law has not yet been unequivocally answered, in my opinion a negative answer is more obvious than an affirmative one. After all, someone who benefits from the, as a result of his own actions, foreseeable actions of third parties to the detriment of the legitimate interests of another cannot already evade any responsibility towards that other person by relying on the fact that the actions are those of third parties and not his own. However, liability requires the producer/dealer of a generic drug to commit a direct or indirect infringement. This cannot be circumvented by simply falling back on the general tort regime of Art. 6:162 of the Civil Code. After all, in cases like the present one, the question of what is or is not permissible (market) conduct in the relationship between generic producer/trader and patent holder is primarily determined by the boundaries drawn by patent law. In other words, it is conceivable that in this relationship (even though tort may sometimes provide additional protection) certain conduct does not qualify as unlawful because it does not qualify as infringement under patent law.

# 4.15

A-G Van Peursem noted in this context that the patent system does not seem to be adequately equipped for the protection of second medical indications.43 The main complications now seem to be (i) what meaning should be given to the element 'manufacture'44 (the process) in the Swiss-type claim and (ii) how to assess whether the drug is intended for the patented second medical indication (the purpose limitation). I outline below some solutions reached in the case law.

Delineation of the scope of protection using manufacture and purpose limitation

## 4.16

Instructive are the decisions on appeal in the English case of Warner-Lambert v. Activis [2015] EWCA Civ 556 and [2016] EWCA Civ 1006 (Floyd LJ), partly because they also demonstrate the different view of Arnold J at first instance.45 This case concerns the second medical (2M-I) patent in the form of Swiss types of claims by Warner-Lambert to use the substance pregabalin to manufacture a drug for the control of neuropathic pain. The free application of the drug is for the treatment of 'general anxiety disorder' (GAD) and epilepsy.

It was held by Floyd LJ as follows.46

- (i) In determining the scope of protection, the element 'manufacture' only has the meaning that 'any manufacturing step' suffices. A doctor prescribing the drug does not manufacture ([2015] EWCA Civ 556 para 119).47
- (ii) If the 'for'/'for' element in the claim were interpreted as 'suitable for' (as is common in process claims), the patentee would be given too much protection, but "the skilled person would understand that the claim so construed could not possibly distinguish over known uses of the known drug" (para 113).48 Therefore, the scope of protection concerns the intentional use of the drug for the patented application (para 118 and):
- "121. Thus the skilled person would understand that the technical subject matter of the claim was concerned with the ultimate end use of the medicament, from which it derived its novelty. The therapeutic treatment is of course new because, and only because, it is carried out with the intention of producing the new therapeutic effect. The prior use of the compound may have in fact produced the effect, for example if a patient taking it for GAD or epilepsy was at the time experiencing pain as well. This demonstrates, to my mind, that it is the intention for which the compound is administered which is at the heart of the invention."
- (iii) There must also be a link between the manufacture and the aforementioned intentional use of the compound for the patented application, because otherwise the manufacturer would not be able to know whether it would infringe. This must be evident from the intention of the manufacturer (para 122; see also [2016] EWCA Civ 1006, para 191). The proceedings initially held at first instance that the manufacturer must have the subjective intention (the intent) to manufacture its generic medicine for the patented application.49 On appeal, it was held that an objective intention is sufficient, i.e. that it is reasonably foreseeable to the manufacturer that its generic medicine will be knowingly used for the patented application. If this is satisfied, then the producer has a duty of care to take reasonable steps to prevent such use50. See Floyd LJ, [2015] EWCA Civ 556, para 127 and, more fully, [2016] EWCA Civ 1006:51
- "208. (...) The intention will be negatived where the manufacturer has taken all reasonable steps within his power to prevent the consequences occurring. In such circumstances his true objective is a lawful one, and one would be entitled to say that the foreseen consequences were not intended, but were an unintended incident of his otherwise lawful activity. (...)."
- (iv) According to [2015] EWCA Civ 556, para 129, direct infringement occurs when the manufacturer "manufactures pregabalin when he knows or foresees that users will intentionally administer it for pain. "52

(v) In his follow-on decision, [2016] EWCA Civ 1006, Floyd LJ clarifies that the intentional use referred to at (ii) does not refer to establishing the intention of the ultimate user (doctor, pharmacist, patient) to use the generic drug for the patented indication,53 but to whether it is reasonably foreseeable to the manufacturer that the generic drug will also be used for the patented indication:

"216 (...) Because elements in this form rely for their novelty on the purpose of the use of the drug, it is only essential that the manufacturer is able to foresee that there will be intentional use of the drug for the new medical indication. Intentional use is to be distinguished from use where the drug is prescribed for a different indication and, without it in any sense being the intention of the treatment, a pain condition is in fact treated.

217. The issue which the judge was called upon to decide was whether Actavis [the manufacturer of the generic drug; A-G] knew or could foresee that at least some of the prescriptions written generically for pregabalin to treat pain [the patented second medical indication; A-G] would in fact be fulfilled with Leceant [the generic drug; A-G]. (...) it would then have been necessary to decide whether, at any of the various dates analysed by the judge, that test of knowledge or foresight was satisfied. If so the judge should have gone on to consider whether Actavis had taken all reasonable steps in their power to prevent Leceant from being used to treat pain."

(vi) In doing so, it is incidentally acknowledged, ([2015] EWCA Civ 556 paras 130-132), that in certain cases, customisation will also be required in the sphere of remedies, such as in the case where (i) the generic drug is also manufactured and used for the free indication or in the case where (ii) it is foreseeable to the manufacturer, despite his adequate precautions, that the drug will be knowingly used for the patented application.

## 4.18

This foreseeability approach was accepted in Rb. Den Haag 5 April 2017, ECLI:NL:RBDHA:2017:3430 in the final judgment in the proceedings on the merits in the Sun/Novartis case:

"3.17. The parties appear to embrace the criterion developed in English case law as regards the interpretation of the term 'for (the treatment of)'. To the extent that Novartis, by its assertion in the post-interlocutory decree that in the Netherlands it is assumed that no 'fault or science requirement' is necessary for committing (direct) patent infringement, (primarily) intended to argue that the generic manufacturer's science is (after all) irrelevant, it overlooks the fact that claim 7 of EP 689 B3 is not an ordinary method claim, but a Swiss form second medical use claim where the science element is indeed relevant.

3.18.

The District Court agrees with the parties and in accordance with the aforementioned English case law that the term 'for (the treatment of)' of a claim formulated in the Swiss way includes a certain mental element regarding science or foreseeability regarding the conscious use of the medicine for the patented indication. The aforementioned criterion will therefore be taken as a starting point in the further assessment."

The District Court concluded that there was an infringement within the meaning of Section 53(1) under b ROW 1995 because Sun knew or at least it was foreseeable to it that its generic medicine would be used intentionally for the treatment of osteoporosis, while it certainly did not do enough to prevent its use for that patented indication.

#### 4.19

In short, this interpretation of a Swiss-type claim implies that the manufacturer commits direct infringement when it uses the generic substance to manufacture a medicine and it is foreseeable that this medicine will be knowingly used for the patented indication. According to MSD (s.t. nos. 122 and 109), the test of whether there is knowledge or foreseeability on the part of the manufacturer regarding the intentional use of the medicine for the patented indication corresponds to the science requirement of section 73 ROW 1995.

## 4.20.1

I note additionally, that in the consideration quoted above at 4.17(iii), Floyd LJ responds to the counter-argument that the foreseeability approach is too broad, because it would imply that the entire production of the generic medicine is to be regarded as a directly obtained product within the meaning of (the English equivalent of) Art 53(1)(b) ROW 1995, even if only part of it would actually be used for the patented application. According to Floyd LJ, this is not the case: if the producer takes reasonable precautions, then he does not infringe within the meaning of this provision so that his entire production does not infringe ([2016] EWCA Civ 1006, paras 202 and 208).

# 4.20.2

This may not provide a solution in the case, where (i) the manufacturer does not take sufficient measures to prevent his generic drug from being used for the patented indication while (ii) it is established that only part of his production will be used for the patented indication (and the other part for the free use). The solution will then possibly be found in limiting the concept of 'directly obtained products' to that quantity of products which it is foreseeable will be used for the patented application. This is also obvious: in this reasoning, the directly obtained products within the meaning of Article 53 (1) under b ROW 1995 have the same limitation as the (process) claim itself, and can therefore be considered to be directly obtained from it. In this way, the production of the generic medicine for free use is left untouched, even if the manufacturer interferes with the holder of the second medical indication patent with part of his production because he takes insufficient precautions in that respect. This prevents the patent holder from receiving too much or too little protection (even though in practice it may be difficult to determine the amount of infringing products very precisely using this yardstick).54

#### 4.21

Disputed is whether the producer can indirectly infringe a Swiss-type claim. (i) In Warner-Lambert v Actavis, it was held at first instance by Arnold, [,2015] EWHC 72 (Pat), that:

"113. In the alternative to its primary claim, Warner-Lambert claims for infringement through the supply of essential means under section 60(2) of the 1977 Act. Counsel for Warner-Lambert did not press this claim. He was right not to do so. There can only be infringement under section 60(2) if there can be infringement by the person supplied or by a user further down the chain of supply (although it is not necessary for there actually to be an infringing act). This is not the case here, since no wholesaler or pharmacist will use Lecaent to prepare a pharmaceutical composition."

but on appeal, Floyd LJ did not rule out the possibility of indirect infringement, partly because ([2015] EWCA Civ 556, para 138:

- "(...) It may be that the invention is put into effect if pregabalin is manufactured by one person and supplied to another who intentionally uses it for the treatment of pain. In those circumstances, a person who supplies pregabalin with the requisite knowledge (i.e. that prescribed in section 60(2) itself) does provide means suitable and intended to put the invention into effect, albeit by the combination of manufacturer and user, rather than by any one person alone. (...)."
- (ii) On the merits of this case, Arnold J then again held that indirect infringement of a Swiss-type claim cannot [2015] EWHC 2548 (Pat):
- "684. The fundamental difficulty with Pfizer's claim under section 60(2) remains, as it has always done, that claims 1 and 3 of the Patent are claims to processes of manufacture, but there is no act of manufacture by any party downstream from Actavis, nor even the prospect of such an act. This is so even if manufacturing (or "preparation", to use the word in the claims) for this purpose includes packaging with appropriate instructions. In particular, there is no act of manufacture by pharmacists, nor any prospect of such an act. It follows that, although there is no difficulty in concluding that Lecaent's active ingredient is "means, relating to an essential element of the invention, for putting the invention into effect", Lecaent is not suitable for putting, or intended to put, the invention into effect: either the invention has already been put into effect by the time that Lecaent leaves Actavis' hands or it is not put into effect at all. Accordingly, I conclude that Actavis have not infringed claims 1 and 3 of the Patent pursuant to section 60(2)."
- (iii) On appeal, Floyd LJ, [2016] EWCA Civ 1006, rejected the argument that only the manufacturer would 'manufacture' (barring the case of labelling for the patented application by the pharmacist), because:

"223. (...) I think there is a danger in translating section 60(2) into a requirement for a 'downstream act of manufacture'. What is required is that means are provided which are for putting the invention into effect.

224. The invention in the present case is the use of pregabalin in the preparation of a pharmaceutical composition for treating pain. As the example of labelling by a pharmacist shows, that process is not completed when the pregabalin has been formulated into a pharmaceutical composition by a manufacturer. The process of preparing the composition can continue through any packaging step performed by the manufacturer and includes the labelling step performed by the pharmacist. (...)

225. I have already concluded when considering direct infringement that the significance of a packaging step is only that it demonstrates the necessary intention. I am therefore unable to understand why other acts of the pharmacist in preparing the composition for delivery to the patient cannot also be regarded as relevant acts of preparation, if done with the necessary intention. I cannot agree with the judge that there is no relevant act of preparation by pharmacists, nor any prospect of such an act."

## 4.22

Arnold J's view was accepted in Rb. Den Haag 25 November 2015, ECLI:NL:RBDHA:2015:14337 in the interlocutory judgment in the proceedings on the merits in the Sun/Novartis case:

"4.53. Novartis interprets these claims as being directed to the preparation of a medicine, which derives its novelty not from its method of manufacture (it was already known) but from its destination (the second medical indication). Those conclusions are indirectly infringed by Sun, Novartis says, in that, before the medicine is administered to the patient, its zoledronic acid 5 mg/100 ml is given the destination osteoporosis at several points in the chain of purchasers (by the prescriber, the pharmacist, the nurse administering it). Novartis therefore believes that at several points in the chain of purchasers, by giving the medicine the destination, the invention is applied. Sun knew or at least should have known that this was going to happen and nevertheless it supplied the essential ingredient by which the infringement was going to be committed. Therefore, it indirectly infringes, Novartis still argues.

## 4.54.

The court is of the opinion that this reasoning is not valid as it is limping on two ideas and is therefore internally contradictory. Starting from a process claim and assuming that the generic zoledronic acid is to be regarded as an essential ingredient, 'for application of the patented invention', as Article 73 ROW phrases it, as far as claim 7 is concerned, cannot be understood in any other way than the preparation ('the preparation' as claim 7 calls it) of the medicine zoledronic acid for the treatment of osteoporosis. However, it is established that the process, i.e. the preparation of the medicine, is (no longer) applied anywhere in the chain after delivery by Sun of the medicine. Novartis' contrary reading that application of the patented invention, 'manufacturing', should be

equated with giving the medicine (product) a purpose can only apply if a Swiss-type claim is regarded as a 'purpose limited product claim', as the EPC 2000 claims are, or at least should be equated with it. Novartis is right not to invoke this. When Novartis argues with a reference to Article 64 (2) EPC that also in the case of a Swiss-type claim the directly obtained result of the process, the medicinal product, is co-protected, it abandons the basis of indirect infringement and enters the field of direct infringement (...)."

In the summary proceedings in the Sun/Novartis case, The Hague Court of Appeal 27 January 2015, ECLI:NL:GHDHA:2015:1769, ruled only on the science requirement referred to in Section 73 ROW 1995, and that point also played a role in cassation.55

## 4.23

Thus, if one assigns (some) significance to the element of 'manufacture' when interpreting the second medical indication patent with Swiss type claims, only those who 'manufacture' will be able to be sued for direct infringement within the meaning of Section 53(1)(b) ROW 1995. That concept offers some stretch, but not unlimited. The manufacturer is the fabricator, but its liability is regulated through what is essentially a standard of care (was the disputed use of the generic drug for the patented indication foreseeable and, if so, were adequate precautions taken). This can be assessed taking into account the circumstances of the case and allows for tailoring. Whether an indirect infringement is possible depends on what is still meant by 'manufacture'.

Delimitation of the scope of protection on the basis of zoning

# 4.24

In contrast to the approach discussed so far, when interpreting a second medical indication patent with Swiss type claims, one could also consider that the process is there only for form's sake, in order to immediately focus attention on destination. Again - cf Rb. Den Haag 5 April 2017, ECLI:NL:RBDHA:2017:3430, para 3.15 - the argument is that the average person skilled in the art knows that these words merely express a fiction of manufacture that was required under EOV 1973 to allow second medical indication patents. The consequence of this argument is now that the scope of protection of Swiss type claims and EPC 2000 claims is the same. In other words, in this approach, Swiss type claims are in fact target product claims disguised as working method claims.

## 4.25.1

An exponent of this approach is BGH 14 June 2016 (Eli Lilly v Actavis):56

"(a) Nach der Rechtsprechung des Senats ist Gegenstand eines auf die Verwendung eines Stoffs zur Behandlung einer Krankheit gerichteten Patentanspruchs die Eignung des Stoffes für einen bestimmten medizinischen Einsatzzweck und damit letztlich eine dem Stoff innewohnende Eigenschaft (...)

Für Ansprüche, die entsprechend der früheren Rechtspraxis des Europäischen Patentamts auf Verwendung des Stoffs zur Herstellung eines Medikaments gerichtet sind, gilt nichts anderes. Diese besondere, als Swiss type claim bezeichnete Anspruchsfassung trug dem Umstand Rechnung, dass die Verwendung eines Stoffs zur Behandlung einer Krankheit nach Auffassung des Europäischen Patentamts der Patentierung nicht zugänglich war. Die stattdessen gewählte Lösung, den Schutz auf die Verwendung zur Herstellung eines Medikaments zu richten, ändert nichts daran, dass der Sache nach eine besondere Eigenschaft des Stoffs geschützt ist, die auch dem hergestellten Medikament innewohnt.

Eine abweichende Beurteilung ergäbe sich selbst dann nicht, wenn Swiss type claims entsprechend ihrem Wortlaut als Ansprüche verstanden würden, die auf den Schutz eines Herstellungsverfahrens gerichtet sind. Ausgehend von einem solchen Verständnis wäre ein nach dem geschützten Verfahren hergestelltes Medikament als unmittelbares Verfahrenserzeugnis anzusehen, das für den geschützten Verwendungszweck gemäß § 9 (http://lexetius.com/PatG/9) Nr. 3 PatG ebenfalls nur durch den Patentinhaber angeboten, in den Verkehr gebracht und gebraucht werden darf. Dies führte im Ergebnis ebenfalls zu einem auf den Verwendungszweck beschränkten Stoffschutz."

Joining this approach for Dutch law are Kleemans & Drok.57 They point out that, although in principle there is a difference between the scope of protection of a purpose-bound process claim and a purpose-bound product claim, this may be thought of differently in Swiss type claims.58

# 4.25.2

The BGH further ruled in Eli Lily v Actavis that the Berufungsgericht had wrongly rejected the alleged indirect infringement because a purpose-bound process claim was relied upon. According to the BGH, the Berufungsgericht thereby failed to recognise that the Swiss-type conclusion in question confers purpose-bound dust protection:

"(b) Die Entscheidung des Berufungsgerichts steht in Widerspruch zu diesen Grundsätzen. Das Berufungsgericht hat offengelassen, ob das Arzneimittel, das die Beklagte vertreiben wil, vor der Verabreichung in einer Kochsalzlösung aufgelöst werden soll und ob dabei ein Gemisch aus Pemetrexedionen und mindestens doppelt so vielen Natriumionen erzeugt wird. Es hat das diesbezügliche Vorbringen der Klägerin schon deshalb als unerheblich angesehen, weil der Patentanspruch auf die Verwendung des Dinatriumsalzes zur Herstellung eines Arzneimittels gerichtet sei.

Hierbei hat das Berufungsgericht unberücksichtigt gelassen, dass auch eine solche Anspruchsfassung beschränkten Stoffschutz gewährt. Eine Verletzung des Klagepatents kann nicht allein wegen dieser Anspruchsfassung abgelehnt werden. Sofern ein Gemisch aus Pemetrexedionen und mindestens doppelt so vielen Natriumionen als Pemetrexeddinatrium im Sinne von Patentanspruch 1 anzusehen ist und ein solches Gemisch vor der bestimmungsgemäßen Verabreichung des Arzneimittels, das die

Beklagte vertreiben will, hergestellt wird, ist vielmehr - in Übereinstimmung mit der nach dem Berufungsurteil ergangenen Entscheidung des Court of Appeal for England and Wales (Floyd LJ, [2015] EWCA Civ 555, Rn. 74-92) - eine mittelbare Patentverletzung zu bejahen."

#### 4.26

In Germany, it is assumed that direct infringement of a second medical indication patent can only occur in the case of "sinnfälige Herrichtung" (English: manifest preparation):59

"(...) It is the "manifest preparation" which makes the act an infringement. The use of a substance for the manufacture of the medicament for a therapeutic use is considered as the beginning of the use for this purpose if there is a manifest preparation. Nevertheless, it remains to be determined in each case independently and taking into account all the circumstances what encompasses such manifest preparation. Regarding a medicament, all acts and means which specifically relate to the relevant medical use or indication are usually considered preparation as such. That includes: preparation of the substance itself if this reveals the intended pupose; the formulation, dosage and packaging; specific instructions for the therapy or dosage regimes; the patient information leaflet; the branding which indicates the specific use or the designation of the product in invoices or shipping documents. In any event it must be clear from those means that the intended use of the medicament is for the patented indication and must be made in direct connection with the product.

Consequently, mere general statements, such as advertisement, which only explain the general effect of a medicament and which do not relate specifically to the patented use are not considered as sufficient manifest preparation. "60

This therefore seems to be broader than the 'only packaging will do' approach that is attributed to German law.61

## 4.27.1

The Landgericht Hamburg assumed indirect infringement in summary judgments of 2 April 2015 in the Lyrica cases because a producer participated in a tender without pointing out that the producer was not allowed to market the product for the patented indication (a carve-out alone was not sufficient). It was considered relevant that this would (almost) automatically entail that a pharmacist would dispense the product for the patented indication:62

"bb) Damit erfüllt der uneingeschränkte Beitritt der Antragsgegnerin zu der Rabattvereinbarung (...) ohne Weiteres die Voraussetzungen des objektiven Tatbestandes § 10 Abs. 1 PatG. Denn der Apotheker erhält unstreitig keine Information über den Grund der ärztlichen Verordnung, d. h. er weiß nicht, für welche Indikation der vor ihm stehende Patient das Präparat erhalten soll. Für die Substitutionsentscheidung des Apothekers ist dies (...) auch nicht von Nöten; denn die Übereinstimmung in einem einzigen Indikationsbereich soll genügen. (...) Apotheker sind damit

aufgrund des bestehenden Rabattvertrages im Falle einer Wirkstoffverordnung (...) gehalten, grundsätzlich nur das rabattierte Präparat - also hier das der Antragsgegnerin - an Patienten abzugeben (...). Es steht daher einer mittelbaren Patentverletzung nicht entgegen, dass die Antragsgegnerin pflichtgemäß ein "skinny labeling" vorgenommen hat. Denn die Patentverletzung ist eine sicher vorauszusehende Folge des einschränkungslosen Beitritts der Antragsgegnerin zum Rabattvertrag."

## 4.27.2

I quote some more considerations, in which the court responds to previous German case law. If the requirement of "sinnfälige Herrichtung" can be imposed at all in a case like the present one, it has been met as the generic product is ready to be used for the patented indication:

- "(cc) Soweit die Antragsgegnerin darauf abstellt, dass es erst noch eines weiteren Schrittes für ein sinnfälliges Herrichten bedarf, kann sie mit diesem Argument gegenüber dem streitgegenständlichen Vorwurf der mittelbaren Patentverletzung nicht durchdringen.
- (1) Es ist bereits fraglich, ob für den Tatbestand der mittelbaren Patentverletzung das Kriterium des sinnfälligen Herrichtens bei einem Verwendungspatent überhaupt von Nöten ist. (...)
- (2) Vorliegend ist das Arzneimittel jedenfalls bereits durch seine Herstellung als sinnfällig für die Anwendung im Sinne des vorliegenden Herstellungsverwendungspatents hergerichtet anzusehen, als dass es ohne Weiteres zur Behandlung von (neuropathischen) Schmerzen verwendet werden kann. Es bedarf keiner weiteren körperlichen Schritte oder Hinzufügung körperlicher Mittel, sondern lediglich einer Zweckbestimmung. Diese Zweck- oder Verwendungsbestimmung trifft vorliegend der substituierende Apotheker, § 129 Abs. 1 S. 2 SGB V (...)."

The present case must be distinguished from the case in which it was only advertisements (and even from the case in which the package leaflet indicates use for the patented indication) now that the applicable regulations oblige the pharmacist to dispense the generic drug also for the patented indication:

"(3) Die Entscheidung des OLG Düsseldorf vom 31.01.2013, Az. I-2 U 54/11 = BeckRS 2013, 11782, zitiert nach juris, wonach allgemeine Werbeankündigungen kein sinnfälliges Herrichten der in Verkehr gebrachten Sache darstellen - und damit keine unmittelbare Patentverletzung zu begründen vermögen -, weil sie nicht den notwendigen unmittelbaren Zusammenhang mit dem Produkt selbst aufweisen, der erst dessen Verwendung in der zweckgerichteten Weise gewährleiste, steht dem nicht entgegen. In dem Verfahren hatte der Kläger "auf ausdrücklichen richterlichen Hinweis bewusst an seinen auf eine unmittelbare Patentverletzung zugeschnittenen Klageanträgen festgehalten und ausdrücklich erklärt [...], Ansprüche wegen mittelbarer Patentverletzung nicht geltend zu machen" und damit dem OLG Düsseldorf die Möglichkeit entzogen, die Frage der mittelbaren Patentverletzung prüfen zu dürfen. Entscheidender Unterschied zu der vorliegenden Konstellation

war zudem, dass derartige, allgemeine Werbeankündigungen naturgemäß keine regulatorischen Rechtsfolgen nach sich ziehen, insbesondere nicht die des § 129 Abs. 1 Sätze 2 und 3 SGB V. Die jeden Apotheker bindenden regulatorischen Vorgaben dieser Normen des Sozialrechts entfalten hingegen eine völlig andere Lenkungswirkung als allgemeine Werbeankündigungen. Ihre Lenkungswirkung übertrifft im Grunde sogar die Lenkungswirkung der Indikationsangaben in der Gebrauchsinformation selbst, weil die Übereinstimmung in einer Indikation bereits genügt und nach Auffassung des Gesetzgebers und maßgeblicher beteiligter Akteure (cf. Anlage ASt 26) auch genügen soll und der Apotheker, wie gesagt, bei seiner Substitutionsentscheidung die Indikation nicht kennt."

It also follows that the LG Hamburg takes a different view of the law than the LG Düsseldorf:

"(5) Das Landgericht Düsseldorf hatte in seiner Ribavirin-Entscheidung vom 24.02.2004, Az. 4a O 12/03 (= GRUR-RR 2004, 193), die mittelbare Verletzung eines Verwendungspatentes verneint und u. a. das Folgende ausgeführt (Rn. 82, zitiert nach juris):

"Eine mittelbare Verletzung des Verwendungspatentes liegt - unter den sonstigen Voraussetzungen des § 10 PatG - vor, wenn der nicht hergerichtete Stoff zum Zweck erfindungsgemäßer Anwendung angeboten oder geliefert wird. Nach den Regeln über den Verfahrensschutz würde dies nicht nur dann gelten, wenn das Anbieten oder Liefern zum gebrauchsfertigen Herrichten, sondern auch zur unmittelbaren Anwendung erfolgt. Jedoch muss bei einem Verwendungspatent, die im Sinne eines zweckgebundenen Sachschutzes für das hergerichtete Erzeugnis verstanden werden, allein den hierfür und nicht den für den Verfahrensschutz geltenden Grundsätzen gefolgt werden. Für die mittelbare Verletzung bedeutet dies, dass sie nur in Betracht kommt, wenn das Anbieten oder Liefern zum gebrauchsfertigen Herrichten, nicht aber zur unmittelbaren Anwendung erfolgt. Gleiches ergibt sich, wenn die Verwendungserfindung durch ein zweckgebundes Stoffpatent geschützt ist [...]."

Dem schließt sich die erkennende Kammer nicht an. Das Präparat der Antragsgegnerin ist bereits mit der Herstellung sinnfällig hergerichtet, jedenfalls vor dem Hintergrund der Vorgaben des § 129 SGB V. Genau mit dieser Problemstellung und den Rechtsfolgen des § 129 Abs. 1 Sätzen 2 und 3 SGB V hatte sich das LG Düsseldorf mangels Sachvortrag nicht auseinanderzusetzen."

Teva (pleading note 45) notes that this judgment is under appeal.

# 4.28

The German approach thus seems to focus on whether the medicine is intended for the patented indication, using the "sinnfälige Herrichtung" requirement to test whether the circumstances indicating such a destination can be related to the defendant's product. Furthermore, indirect infringement is considered possible.

## 4.29

It is against this background that I discuss the plea.63

Part 1 (scope of protection)

#### 4.30

This part refers to paragraphs 4.2, 4.4 and 4.5 and contests in essence that the scope of protection of an SG-I patent is limited to the situation where a third party specifically indicates that the substance is intended for the subgroup. The scope of protection of inventions cannot be defined in the abstract, including by category, at least not in the way the court does (section 1.1). The court should have determined the scope of protection using a test in concreto (section 1.2). The court's standard does not provide sufficient protection to the holder of an SG-I patent (section 1.3) and wrongly distinguishes it from 2M-I patents (section 1.6). The court did not provide sufficient reasons for its judgment on the scope of protection in light of MSD's contentions (parts 1.2 and 1.3) and the applicable standard (parts 1.4, 1.5 and 1.6). Part 1.7 does not contain an independent complaint.

These complaints can be discussed together.

#### 4.31.1

Let me start by noting that the court, on the basis of the patent claims and the description64, establishes what EP 861 is based on (para 4.1) and finds that EP 861 is an SG-I patent (para 4.2). Referring to the Protocol, the court considers that the patentee's protection should not go beyond what is justified by his invention (para 4.2).

#### 4.31.2

If I see it correctly, the court of appeal then includes reserved actions in its interpretation of the patent (para 4.2),65 as a tool to determine what the patent adds to the prior art and thus to adjust the scope of protection of the patent accordingly. Indeed, the court asks when the marketing of the substance realises the benefits of the 'new' use of the substance (para 4.3) and the use for the subgroup (para 4.4) respectively. This approach can be traced back to Teva's pleading in appeal no. 21 to which the court of appeal refers. There, Teva argues that infringement requires Teva to market its ribavirin specifically for the patented selection namely by pursuing the selection in combination with the treatment duration. In other cases, according to Teva, there would only be marketing of ribavirin for the already known, free use for the 'broad' group of patients. The court accepts this idea and translates it - I see correctly: with some nuances to be mentioned below - into the interpretation of the patent.

## 4.31.3

The court considers in paragraph 4.4 (fourth sentence): "In order to realise the benefits of an SG-I invention, it is therefore necessary that the substance is used specifically for the subgroup (and, in this case, moreover, for the specific treatment period)." The court then concludes in paragraph 4.4 (fifth sentence) that the scope of protection of an SG-I patent, and thus also of EP 861, is "limited to the situation where it is specifically stated by a third party that the substance is intended for the subgroup (and, in this case, also for the specific treatment duration)."

#### 4.32

Rov. 4.4 (fourth sentence) is in itself consistent with the fact that EP 861 contains purpose-bound claims that refer to the use of ribavirin for a specific subgroup and treatment duration.66 I note that the court of appeal, in rov. 4.4, focuses its interpretation of the patent directly on the question of when the drug is intended for the patented second medical indication. The court does not address the process expressed in EP 861 ('preparing').67 Nor does the court address any 'mental element' such as 'intent' or 'reasonable foreseeability' on the part of the generic manufacturer or trader.68 The court of appeal does not adopt Teva's terminology 'pursuing' and does not refer to the continuation of Teva's contentions (pleading in appeal no. 22), that it is also required that Teva also deliberately markets its ribavirin specifically for the selection referred to in EP 861, because this is what is meant by the word 'for' in 'treating for' in Swiss-type claims (with reference to the opinion of Arnold J). Nor does the court examine whether the word "for" in such claims could refer to objective foreseeability of the patented use of the plea (as had been assumed by Floyd LJ and recently adopted by Rb. Den Haag 5 April 2017, ECLI:NL:RBDHA:2017:3430).

As the court only focuses on the question of when the drug is used for the patented second medical indication, I limit my discussion to that.

## 4.33

The court understandably seeks to distinguish between use of the generic medicine for the indication already known from Grint and its use for the indication referred to in EP 861. After all, in determining the scope of protection of an SG-I patent, something must be done with the fact that the patients who currently fall into the subgroup defined by the patent were or could be treated with the drug before the SG-I patent was granted. Specifically, when ribavirin is used for the already known indication (Grint: patients with chronic hepatitis C) and treatment duration (Grint: 6 to 12 months), there may indeed be among the treated patients who (assuming that the relevant data are known, appear to) meet the characteristics listed in EP 861 (naive patient with HCV genotype 1 infection and a viral load of more than 2 million copies per ml of serum) and treatment duration (about 40-50 weeks). How should we now distinguish between group and subgroup use of ribavirin?

# 4.34

At this point, I think a distinction should be made between the situation before EP 861 was granted and the situation after it was granted. Before EP 861 was granted, patients with the characteristics later revealed in EP 861 belonged to the whole group - there was no subgroup at that time. Assuming that EP 861 is new and inventive, it can be said that before the subgroup was defined in EP 861, it did

not exist as such. The contention that the subgroup was also treated with ribavirin before the granting of EP 861 is strictly speaking intrinsically contradictory because it relies on knowledge that was first revealed by EP 861.69 Only after the granting of EP 861 can a meaningful distinction be made between the group and the subgroup, i.e. the question of whether the generic medicine is intended to treat a patient belonging to the group or to the subgroup.

## 4.35

Now, one possible view is that, after granting EP 861, patients with the characteristics revealed in EP 861 no longer belong to the group, but only to the subgroup. By definition, the subgroup is separated from the rest of the group. In this view, the scope of protection of EP 861 would extend to any use of ribavirin to treat patients belonging to the subgroup.

#### 4.36

However, the court seems to take a different view which is that, even after granting EP 861, the group and the subgroup are not necessarily separated. If a patient with the characteristics referred to in EP 861 is treated with ribavirin, it will have to be considered whether that treatment is based on an application of Grint or an application of EP 861. Only the latter case falls within the scope of protection of EP 861, according to the court.

In the fourth sentence of paragraph 4.4, the court of appeal formulates the test that the substance is used specifically for the subgroup (and in this case for the specific treatment period). The reason for this is that, according to the court of appeal, only then the use of the substance is based on the new knowledge and the benefits of EP 861 are realised.70 The word 'specific', which delimits the scope of protection of EP 861, thus refers to use of the substance that is aimed at the patient subgroup and treatment duration defined in EP 861.

Thus, in this reasoning, it is also possible that the substance is used (not specifically, but) 'accidentally' in a case covered by EP 861. Then, as I understand the court, Grint is still applied. This is what I think the court of appeal is referring to in the third sentence of paragraph 4.4: "After all, it was already known in the prior art to use the substance for the group of patients to which the subgroup belongs so that that substance could also be used to treat that subgroup." The court thereby rejects the idea that the scope of protection of an SG-I patent such as EP 861 extends to the mere fact that a patient belonging to the subgroup is treated with the substance.

# 4.37

If my reading of the judgment is correct, then the demarcation problem between the free indication and the second medical indication in SG-I patents referred to at 4.36, for which the court of appeal sought a solution, may nevertheless be akin to the demarcation problem in 2M-I patents. Indeed, even with 2M-I patents, the question may arise whether a drug is used 'accidentally' or 'specifically' for the second indication. I refer to the example of Floyd LJ on the use of pregabalin for the free

indication where pain management (the second indication) also occurs, but without the drug being prescribed for pain management.71

#### 4.38

In my view, the question whether the scope of protection of an SG-I patent covers any use of the substance for the subgroup or only 'specific' use of the substance for the subgroup cannot be answered in the abstract, but will have to be determined by interpretation of the patent. In this context, the extent to which the SG-I patent distinguishes itself from the prior art could be relevant, for example. For example, if the existing knowledge includes the application of the substance for the known therapeutic treatment but the practice makes little use of it (e.g. because this application offers variable results for the entire patient group and is therefore not that successful while more successful alternative means are available and used), an SG-I patent might add a lot to that knowledge (e.g. when the substance does turn out to work well especially in a further defined subgroup). In that case, it might be more obvious to conclude that the scope of protection of the SG-I patent extends to any use of the substance for the subgroup.

## 4.39

In any case, it does not seem correct to me to limit the scope of protection described in paragraph 4.4 (fourth sentence) on the basis of 'specific use', as the court of appeal does in paragraph 4.4 (fifth sentence), to cases where a third party specifically indicates that the substance is intended for the subgroup. I think the plea rightly complains about this.

## 4.40.1

If the third party refers to the manufacturer/dealer who indicates on the SmPC and/or package leaflet that the drug is intended for the patented indication - the situation to which the court of appeal seems to be referring according to paragraph 5.2 - then the scope of protection of the patent is indeed at issue. But, based on the way the court delineates the scope of protection of the SG-I patent, even outside that case, it is conceivable that the manufacturer realises the benefits of the patent or that the generic substance is used specifically for the subgroup.

# 4.40.2

Thus, Blomme, in his note under the judgment under appeal, notes that the benefits of the patented in SG-I patents (as in 2M-I patents) can also be realised if the concrete facts and circumstances would show that the third party has entered into a preferential agreement with a health insurer that the specific subgroup will be treated with its generic drug. 72 The manufacturer/dealer then realises the benefits of the patent without indicating (on the SmPC and/or package leaflet) that its drug is intended for the subgroup.

## 4.40.3

It is also conceivable that the generic substance is used specifically for the subgroup without the manufacturer/dealer indicating (on the SmPC and/or package leaflet) that the substance is intended for it. Even despite an in itself adequate carve-out in the SmPC and/or package leaflet, this may be the case and the manufacturer/dealer may therefore realise the benefits of the patent. Medical practitioners are not dependent on the information provided with the drug itself for their information gathering and can use that drug even without that information ('specifically') for the patented indication. It then remains to be seen whether the manufacturer/dealer infringes EP 861 in those circumstances, but the scope of protection of EP 861 is then at issue

## 4.41

MSD (pleading notes No 6) points out that the limited scope of protection described by the court of appeal ultimately in paragraph 4.4 (fifth sentence) would "mean that by merely including a carve-out in the SmPC, a generic provider can escape infringement even if he knows that his product is widely used for the patented invention and therefore also knows that that carve-out is ineffective. There is then simply no reasonable protection for the patentee of SG-I patents." I tend to share this criticism.

## 4.42

Finally, I note that the scope of protection described by the court of appeal in paragraph 4.4 (fifth sentence) already seems to cut off any discussion of the possibility of indirect infringement as that scope of protection on balance incorporates the existence of direct infringement (i.e.: specifically stating that the substance is intended for the subgroup). That may not matter for Swiss-type claims if it should be assumed that they cannot be subject to indirect infringement, but in any case mortgages the interpretation of SG-I patents in the form of EPC 2000 claims.

# 4.43.1

I conclude as follows. To the extent that the plea directs complaints against paragraph 4.2, in my view it cannot be said that the court, as argued by section 1.1, determined the scope of protection of EP 861 in the abstract and not on the basis of a test in concreto (even if the distinction between SG-I patents and 2M-I patents is, in my view, ultimately overstated). In my view, the court included in its judgment the perspective of the average person skilled in the art (cf. paragraph 5.2), contrary to the legal complaint of section 1.2.

I think the section rightly complains about the way the court elaborated on the distinction between 2M-I patents and SG-I patents in paragraph 4.4. In my opinion, the complaints of parts 1.2 and 1.3 directed to that point succeed. The reasoning complaint in section 1.2 (repeated in section 1.3) also succeeds. There, the plea rightly complains that the court of appeal's opinion on the scope of protection of EP 861 is insufficiently (comprehensibly) reasoned in light of the viewpoints put forward by MSD that (i) on the priority date there were still many uncertainties in connection with the combination therapy of interferon alpha and ribavirin, (ii) the prior art precisely clearly led away from the doctrine of the invention, (iii) the invention constituted a surprising success and (iv) the therapy according to the invention is also a great success in practice. Indeed, it is not clear from the court's reasoning whether, and if so to what extent, the court included these contentions in its

judgment while they may be relevant to the delineation of the scope of protection (see at 4.38). In any event, the consideration in paragraph 4.1, that EP 861 "merely relies" on the finding etc. seems to me an insufficient response to these contentions of MSD. In this connection, I believe that section 1.3 also succeeds insofar as it takes issue with the fourth sentence of paragraph 4.4. In so far as the substantiation complaint of part 1.4 also concerns the assertions referred to in parts 1.2 and 1.3, it also succeeds.

#### 4.43.2

Subsection 1.5 is presented insofar as the court of appeal only intended to express that the category to which the patent belongs should (also) be taken into account in the infringement question and argues that its judgment is then insufficiently comprehensible reasoning. This complaint fails for lack of factual basis since, according to paragraphs 4.1-4.5 and the heading above these considerations, the court of appeal considers the category of the patent to be precisely important for determining the scope of protection.

## 4.43.3

Part 1.6 addresses a further separate complaint against paragraph 4.5 which varies from the complaints of part 1 already discussed; part 1.6 therefore needs no further consideration. Moreover, section 1.7 rightly argues that the success of section 1 also affects this consideration.

Part 1.7 also rightly argues that the success of part 1 means that the judgments in paragraphs 5.2-5-5 (paragraph 5.1 contains only an assumption by the court of appeal), paragraphs 6.2-6.5 (paragraph 6.1 contains only an assumption by the court of appeal), paragraph 7.1 and paragraphs 7.3-7.5 cannot stand.

Although section 1.7 also refers to paragraph 7.2, I believe that this consideration is not affected by the success of section 1. In it the court of appeal considers, with reasons, that it cannot be assumed that the SmPCs and package leaflets (not provided with carve-outs) from before 22 January 2010 still influenced the knowledge of the public and thus the prescribing behaviour of doctors now that Teva's ribavirin came on the market a considerable time later (in June or October 2011). There is no further complaint against paragraph 7.2.

# 4.44

Teva (pleading no. 3.11) still argues that MSD has no interest in part 1, because - as I understand it even if this part were to succeed, "there is no infringement since Teva has, after all, applied a carve-out in which it explicitly excluded that subgroup". This defence fails. Indeed, the court's finding of direct infringement builds on the finding successfully challenged by component 1. Furthermore, the defence overlooks the fact that the judgment challenged by component 1 also underlies the court's judgment on indirect infringement.

#### Parts 2 to 6

#### 4.45.1

Parts 2 to 6, which address complaints against the judgments on direct infringement, indirect infringement, the offer of proof and the claim of unlawful infringement and against the conclusion and the operative part of the judgment, need no further discussion. After cassation and reference, these issues may be raised again if necessary. For the sake of completeness, I note that, in my view, these parts succeed.

## 4.45.2

Subsection 2 rightly complains that the opinion of the court of appeal in paragraphs 5.2-5.5, that direct infringement in any case requires that the average person skilled in the art will believe, based on the SmPC and/or the leaflet accompanying Teva's generic ribavirin, that it is specifically intended for the subgroup referred to in paragraph 4.1, is an error of law. This opinion, according to paragraph 5.2, builds on the erroneous determination of the scope of protection in paragraph 4.4.

#### 4.45.3

Subsection 3 rightly complains about the opinion in paragraphs 6.2-6.5 on indirect infringement, which, according to paragraph 6.5, also builds on the incorrect determination of the scope of protection in paragraph 4.4. The complaint that the court of appeal misinterpreted the essential element requirement of section 73 ROW 1995 also succeeds in my view, as will be explained below.

## 4.45.4

Part 4 correctly complains that the court of appeal passed over MSD's offer to prove that doctors and pharmacists apply the invention of EP 861 by prescribing Teva's ribavirin and/or patients by using it. Such evidence is indeed pertinent as it could potentially prove whether Teva's product falls within the scope of protection of the patient, i.e. whether Teva's generic ribavirin is also (purposefully) used (or is likely to be used) for the patient subgroup and treatment duration described in EP 861.

## 4.45.5

Subsection 5 is directed against the judgment in paragraph 7.3 that there is no room to rule differently on the tort claim than on the patent infringement claims since MSD did not base its tort claim sec on different facts than its claims of direct and indirect patent infringement. Since the judgment on direct and indirect infringement cannot stand, the same applies to this judgment.

#### 4.45.6

Finally, section 6 contains a sweeping complaint which, in view of the foregoing, is also rightly proposed.

### Additional comments

#### 4.46

With a view to the possible post cassation and reference debate, I make some additional comments on Swiss-type claims and on the Senseo judgment.

#### 4.47

MSD (s.t. 89 and 122) argues for adherence to the 'foreseeability approach' and Teva (pleading 3.8, 3.14) to the 'eyeball approach' from the English case Warner-Lambert v. Actavis. As I pointed out above, those approaches relate to aspects of the interpretation of the patent on which the court has not yet ruled at all in the present case.

Nor did the court address the question of indirect infringement of a Swiss-type claim. Teva (pleading no. 7.5 et seq.) raises that this is not possible so that for that reason part 3 lacks relevance. MSD (rejoinder no. 8 et seq.) disputes that position, but primarily takes the view that this point cannot be raised in these cassation proceedings.

In my opinion, the cassation appeal can be assessed without addressing these issues. In case the Supreme Court does wish to devote considerations (superfluous) to this, I note the following.

# 4.48

All of these issues involve the question of what meaning should be given to the modus operandi contained in a Swiss-type claim. Here a choice has to be made. In my view, it is clear, that the background to such claims entails that the element of manufacture contained therein is a fiction.

The viewpoint that, when interpreting a patent, "the invention idea lying behind the words of the claims" serves to avoid "an interpretation based solely on the literal meaning of the words and therefore perhaps too limited or unnecessarily broad for the reasonable protection of the patentee" - see most recently HR 5 February 2016 (Bayer/Sandoz) - provides a starting point to give the appropriate weight to the fictitious manufacturing step in a Swiss-type claim.

In my view, that weight is that, given this fiction, the element 'manufacture' is a hollow phrase: it is there, but it does not in reality refer to the invention to be protected. The element is thus, in my view, fundamentally meaningless in terms of determining the scope of protection of a Swiss type claim. I feel supported in that thought by the fact that when the grant was made 'overnight' (29 January 2011) Swiss type claims were banned and a switch was made to EPC 2000 claims.73 Surely

then, convergence of the two types of claims should also be sought when determining the scope of protection.

## 4.49

In my view, this means that the manufacturing step in a Swiss type of claim should not mean that the patentee is not entitled to protection in situations where such protection is justified. The situation where the manufacturer/dealer of a generic drug knows or can foresee with a sufficient degree of certainty that its drug, notwithstanding a carve-out in the SmPC or package leaflet, will be used for the patented indication but does not take adequate measures to prevent such use is, in my view, such a situation. In my view, this is also the normative premise underlying the opinion of the court of appeal and the Supreme Court in the Sun/Novartis case, although that opinion was given in a different legal framework (the science requirement of section 73(1) ROW 1995). I agree with A-G Van Peursem that in doing so, it is sufficient that the measures make the infringement more difficult and seriously discourage the use of the drug for the patented indication.74 After all, the producer/dealer of the generic drug cannot be expected to completely prevent/eliminate the infringement, as this is not within its power.

#### 4.50

In my view, it is possible to find room for this in the infringement provisions of the ROW. Based on the modus operandi (paying lip service to the text of the conclusion), it can be said that the producer commits direct infringement within the meaning of Section 53(1)(b) ROW 1995 in the situation referred to above. In that situation, the producer manufactures a drug that will (also) be foreseeably used for the patented indication so that, in the absence of adequate precautions to prevent that use, it can be deemed to be (also) intended by him for that purpose. Ignoring the method entirely, application of Section 53(1)(a) ROW 1995 comes into the picture. In my opinion, this is not necessary, as the route of Section 53(1)(b) is also open.

Assuming that the method is a fiction, the situation would be viewed through the glasses of art. 73 subsection 1 of the ROW 1995, the question is not whether the method is applied by others further down the chain, but whether the means is intended for use for the patented indication by these others. This provision already provides for a foreseeability test in the form of the science requirement addressed by HR 14 April 2017 (Sun/Novartis).

In any case, as already discussed (at 4.20.2), it will be necessary to distinguish between the production of the generic medicine for the free indication and the production for the patented indication, by examining which part of the production is foreseeable that it will be used for the patented indication. To the extent that this is the case, in my view one of the infringement categories can be relied upon.

4.51

Incidentally (also apart from the above), it seems at least desirable to say something in this case about the "means relating to an essential element" requirement of Section 73(1) ROW 1995. Indeed, the court held that generic ribavirin is not a means concerning an essential element of the invention of EP 861. This creates a separate barrier to indirect infringement of an SG-I patent. I limit my discussion to the court's interpretation of the Supreme Court's Senseo judgment. 75

4.52

In HR 31 October 2003 (Senseo) it was considered:76

"3.4.1 Part I of the plea opposes paragraph 13-15 of the judgment under appeal with complaints of law and reasoning. The complaint in part I(i) is that the court erred, or at least failed to give sufficient reasons, in finding that the patent removes the disadvantages of the US patent, from which it is delineated in the patent specification, removes by modification of the holder of the assembly and not (also) by modification of the coffee bag, and inferred that the coffee bag in question, which was known in the prior art as such, or as part of another assembly, did not qualify as a means relating to an essential element of the invention.

## 3.4.2

To the extent that the section complains about the court of appeal's interpretation of the patent in this way, it comes up against what has been considered above under 3.3.2.77 It also fails otherwise. The mere fact that an appropriate coffee bump is necessary for the application of the patented device does not automatically mean that this bump constitutes a means concerning an essential element of the invention. Apparently, and in the light of the court's interpretation of the patent, not incomprehensibly, the court considered that the suitable coffee pouch fitted to the holder does not constitute an element of that which, according to the patent specification, distinguishes the teaching of the patent from the prior art. That judgment does not show an error of law."

#### 4.53

This ruling has been criticised as having the result that Section 73 ROW 1995 would actually no longer provide effective protection for indirect patent infringement, as it would effectively limit protection to what is independently patentable. 78 It is also doubted whether "that by which, according to the patent specification, the patent doctrine distinguishes itself from the prior art" provides an appropriate criterion to indicate whether there is a means relating to an essential element within the meaning of Article 73(1) ROW 1995,79 although support for this can also be found.80 The plea invites the Supreme Court to follow the approach of German case law (see, in particular, sections 3.2-3.3 and MSD s.t. nos. 105 and 125-127).

#### 4.54

According to the court's reading in paragraphs 6.4 and 6.5 of its now contested judgment, the Supreme Court expressed in the Senseo judgment that a 'means relating to an essential element of

the invention' as referred to in Article 73(1) ROW constitutes that by which, according to the patent specification, the doctrine of the patent is distinguished from the prior art. I wonder whether this should be read into these Supreme Court considerations.

#### 4.55

In the Court of Appeal's interpretation of the patent in the Senseo case - which the Supreme Court leaves to the Court of Appeal: para 3.4.2, first sentence - this does not include the coffee bump itself. The patent concerned the modification of the holder of the assembly, in particular the placement of the grooves in the holder. The use of a coffee bump fitting in the holder falls outside the scope of protection of the patent thus construed. The court (para 13) equates the coffee bag with the use of water to make coffee. 81 On the basis of this interpretation of the patent by the court of appeal, the Supreme Court therefore defines the coffee bump in paragraph 3.4.2 as something necessary for the application of the patented device. Now there is a difference of opinion as to whether the coffee bump in this case indeed has only this 'subordinate' status. But it must be assumed so, if the Supreme Court's considerations are read.

## 4.56

In his opinion under 46 for HR 13 January 2006, ECLI:NL:HR:2006:AU3256, A-G Huydecoper summarised the Senseo judgment on this point as follows:

"In HR 31 October 2003, BIE 2004, 47, para 3.4.2, it was held that a provision that is indeed82 necessary for the application of a patent does not therefore necessarily constitute a means relating to an essential element of the invention; and that this may be thought of differently, in particular, if the provision in question does not constitute an element of that by which the doctrine of the patent is distinguished from the prior art."

## 4.57

The Supreme Court's consideration that the mere circumstance that the use of a coffee husk (or water, I would add) is necessary for the application of the patented device does not automatically mean that this bump constitutes a means concerning an essential element of the invention is focused on the circumstances of the case and does not provide any information as to what is to be understood more generally as a "means concerning an essential element of the invention". This consideration does not give rise to the court's reading in paragraphs 6.4-6.5 of the judgment currently under appeal. In the remainder of paragraph 3.4.2 of the Senseo judgment, the Supreme Court considers that an opinion attributed by it to the court of appeal is not incorrect or incomprehensible. In my view, that consideration too cannot be generalised to the applicable standard.

4.58

In view of the foregoing, the court of appeal assumed, in my opinion, an excessively strict interpretation of the Senseo judgment. This is rightly complained about in section 3, in particular section 3.10. Also, in my opinion, section 3.11 rightly points out the tension between rulings 6.3 ('an essential element of the invention' is not limited to an element that is in itself new or inventive) and rulings 6.4-6.5 (a 'means relating to an essential element' is that by which, according to the patent specification, the patent distinguishes itself from the prior art). After referral, if the court gets to the indirect infringement question, I believe it will have to re-examine whether the substance ribavirin (which substance - unlike the coffee can in the Senseo case - does fall within the scope of protection of the patent) constitutes a means concerning an essential element of the invention.83

specification, the patent distinguishes itself from the prior art). After referral, if the court gets to the indirect infringement question, I believe it will have to re-examine whether the substance ribavirin (which substance - unlike the coffee can in the Senseo case - does fall within the scope of protection of the patent) constitutes a means concerning an essential element of the invention.83
Litigation costs
4.59
The parties have agreed on the amount of the costs to be awarded in cassation within the meaning of Section 1019h Rv, namely an amount of EUR 100,000.84
5Conclusion
The conclusion is to set aside the judgment under appeal.
The Procurator General at the
Supreme Court of the Netherlands
A-G
1Rov. 1.1-1.11 of the contested judgment of the Court of Appeal of The Hague of 14 July 2015, ECLI:NL:GHDHA:2015:1899, BIE 2015/53 m.nt. T.M. Blomme.
2The judgment under appeal further states that Schering Corporation is the holder of the patent. Schering Corporation is now called MSD. See Advisory Opinion no. 1.2.
3In the judgment under appeal, EP 681 appears here by mistake.

4In the judgment under appeal, HVC appears here erroneously.

5Court of The Hague 10 November 2010, IEPT20101110.

6Court of Appeal of The Hague 14 July 2015, ECLI:NL:GHDHA:2015:1899, BIE 2015/53 cf. T.M. Blomme.

7See Teva rejoinder no. 1.1.

8See, for example, Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, Industrial Property 1 (2016), nos. 3.3.7.21 - 3.3.7.22; M-H.D.B. Schutjens, Patent Law and Medicines (diss. 1993), p. 173 et seq.

9The same applies to the discovery of third and further medical indications, but this can be left aside for now.

10See Case Law of the Boards of Appeal of the European Patent Office (Eighth Edition, July 2016), I.C.7.2.4 (Novelty of the therapeutic application).

11See T 1399/04, quoted in part above at 2.4.2. See also S. Dack, Claiming medical indications, BIE 2010, pp. 90 and 91.

12The court speaks of a treatment period in paragraph 4.4. MSD (pleading notes no. 5) speaks of a dosage regime.

13See, for example, A. Benyamini, Patent Infringement in the European Community, 1993, IIC Studies, p. 94: "Altogether, the second medical use claim approved by the EPO is a process claim for the manufacture of a known medicine for a specific novel application."

14GKB 5 December 1984, G 5/83.

15See more extensively Dr J. Meier, European Patent Office, in: J. Bühling et al, Patent Protection for Second Medical Uses (AIPPI Law Series 2016), pp. 5-13; Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, Industrial Property I (2016), no. 3.3.3.22; R.M. Kleemans and J.D. Drok, Interpretation of Swiss-type claims and EPC 2000 claims, IER 2017/3; S. Dack, Claiming medical indications, BIE 2010, pp. 83-92.

16Act revising the Convention on the Grant of European Patents, Munich 29 November 2000, Trb. 2002/9 and Trb. 2002/64 and 170 (translation). Entry into force: 13 December 2007, Trb. 2007/233.

17Stb. 2006/22. Entry into force: 13 December 2007, Trb. 2007/342.

18Art. 54 paragraph 4 EOV and Art. 4 paragraph 5 ROW 1995 refer to initial medical indications.

19GKB 19 February 2010, G 2/08, 7.1.2.

20GKB 19 February 2010, G2/08, 7.1.4.

21Another case is currently pending before the Supreme Court on the scope of protection of a patent. It concerns the cassation with No 16/02891 against the judgment of the Court of Appeal of The Hague of 16 February 2016, ECLI:NL:GHDHA:2016:339, BIE 2016/23 (Astrazeneca c.s./Resolution).

22HR 5 February 2016, ECLI:NL:HR:2016:196, NJ 2016/496, cf. CH. Gielen; Ars Aequi AA20160650, m.nt. Th.C.J.A. van Engelen; BIE 2016/15, m.nt. J.H.J. den Hartog and T.M. Blomme (Bayer/Sandoz). Before that, HR 4 April 2014, ECLI:NL:HR:2014:816, NJ 2015/11, cf. Ch. Gielen; IER 2014/65, m.nt. T.H.B. Iserief and A.M.E. Verschuur; Ars Aequi AA 20140743, m.nt. Th. C.J.A. van Engelen, paras 3.4.2 and 3.5.2 (Medinol/Abbott).

23A-G Van Peursem, opinion sub 2.8 for Sun/Novartis, referring to A-G Huydecoper, opinion sub 22-23 for HR 25 May 2012, ECLI:NL:HR:2012:BV3680, NJ 2013/68 (AGA/Occlutech).

24MSD (s.t. no. 56) points out that it has argued that Teva's generic ribavirin is covered by EP 861 as doctors and pharmacists prescribe Teva's product for the patented indication. Teva (Teva pleading no. 1.3; Teva rejoinder no. 2.9) has disputed that its generic product is used or threatened to be used for the patented indication. MSD in itself rightly points out that it can be presumptively assumed in cassation that Teva's generic ribavirin is covered by EP 861, since this has been asserted by it and the court of appeal has not given an opinion on this. In this connection, see below the treatment of part 4 (under 4.45.4).

25Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, Industrial Property I (2016), no 3.5.4.1.

26The reserved actions are regulated by national law. See Article 64(1) EPC, where Article 64(2) EPC does require that, in the case of a process patent, the protection derived from the patent extends to the product obtained directly by that process (cf. Article 53(1)(b) ROW 1995).

27Huydecoper/Van der Kooij/Van Nispen/Cohen Jehoram, Industrial Property I (2016), no 3.5.5.12.

28See on background and function of this provision further A-G Van Peursem, opinion sub 2.17 for HR 14 April 2017, ECLI:NL:HR:2017:692 (Sun/Novartis).

29HR 14 April 2017, ECLI:NL:HR:2017:692 (Sun/Novartis), para 3.5.2.

30S. Dack, Claiming medical indications, BIE 2010, pp. 83-84; MSD s.t. no 35.

31Which may still be relevant whether it is also mentioned, that this use of the drug is not allowed because it would infringe a (second medical indication) patent.

32The removal of the patented indication from the SmPC is permitted by virtue of art. 11 Directive 2001/83/EC.

33See para 1.6 of the judgment under appeal and cf. HR 14 April 2017, ECLI:NL:HR:2017:692 (Sun/Novartis), para 3.1 sub (viii).

34According to MSD s.t. no. 29, the starting point is that doctors (should) base their prescribing policy on the full-label version.

35According to Vzr. Rb Den Haag 15 January 2016, ECLI:NL:RBDHA:2016:334, JGR 2016/3 m.nt. Lisman (Warner-Lambert/CBG), the CBG acted in violation of the social due care to be observed towards the holder of the second medical indication patent, by reporting the patented indication without duty and in defiance of the request of the applicant for the marketing authorisation in question without warning or even indicating that it was a patented indication. By interlocutory judgment of 14 March 2017, the Court of Appeal of The Hague ruled in these interim proceedings to consider asking preliminary questions to the ECJ, according to Rb. Den Haag 5 April 2017, ECLI:NL:RBDHA:2017:3430, para 2.30.

36 Doctors' prescribing policies vary from country to country. For an overview, see: Kleist et al, Second Medical use Patents for Medicinal Products in the EU: When is Being Skinny not enough?,

Parmaceut Reg Affairs 2016, 5:2. See also J. Bühling et al, Patent Protection for Second Medical Uses (AIPPI Law Series 2016).

37MSD s.t. No 32 points to the Guideline on Effective Prescribing of Medicines for Medical Specialists (March 2011), pp. 8 and 11, which states: "To save costs, for more than 15 years general practitioners have been actively encouraged to prescribe by substance name so that pharmacists can dispense generic drugs." and "In principle, prescribing is done by substance name. The idea is that pharmacists can dispense generic versions of the drug without any problems if they are available. However, the advice as laid down in the guide to medicine substitution drawn up by the KNMP in January 2010 must be followed (see box). For drugs with a narrow therapeutic range and for conditions where even minor variations in bioavailability or bioequivalence cannot be accepted, brand-name prescriptions can be made. A brief explanation on the prescription can then show the prescribing doctor's intention."

38MSD s.t. no. 34 refers to the KNMP manual on drug substitution.

39Cf. HR 14 April 2017, ECLI:NL:HR:2017:692 (Sun/Novartis), para 3.1 sub (x).

40In the present case, (imminent) use was not an issue in the proceedings before the court, see Rb. Den Haag 10 November 2010, IEPT20101110, paras 2.13 and 4.11.

41See also MSD s.t. no. 11 and Teva rejoinder no. 2.1 note 5.

42For an overview of the issues, see also the Working Guidelines at Q238 (Second medical use and other second indication claims), available at http://aippi.org/wp-content/uploads/committees/238/WG238English.pdf. See also MSD s.t. no. 11 and Teva rejoinder no. 2.1 note 5.

43Also A-G Van Peursem, opinion sub 2.16 for Sun/Novartis.

44Or an equivalent as 'prepare'.

45There are first and second instance judgments. The UK Supreme Court granted leave to refer the case to it on 6 March 2017.

46In [2016] EWCA Civ 1006, para 184 et seq, it is stated that the recitals are obiter dicta because the claims of the patent relied on by Warner-Lambert are 'invalid'.

47See on the pharmacist the follow-on judgment of Floyd LJ [2016] EWCA Civ 1006, paras 191 et seq and further the discussion between Arnold J and Floyd LJ referred to at 4.21. A Danish court ruled on 25 June 2015 (A-6-15) that pharmacies directly infringed a Warner-Lambert/Pfizer second medical use patent because they had labelled Krka's generic pregabilin with the patented second medical indication, thereby performing the final manufacturing step. On this ruling, see Floyd LJ [2016] EWCA Civ 1006, para 196, and R.M. Kleemans & J.D. Drok, Interpretation of Swiss-type claims and EPC 2000 claims, IER 2017/3, p. 20

48Cf MSD s.t. nos 14-16 and 73, where reference is also made to a judgment to this effect by the Barcelona Court of Appeal of 5 July 2016

49Arnold J [2015] EWHC 223 (Pat), para 8.

50Cf. the TGI Paris ruling of 13 and 26 October 2015 (15/58725) in Warner-Lambert et al/Sandoz et al that there was no infringement because - in short - Sandoz used a skinny label and had sent an information e-mail to doctors and pharmacists prior to the launch of its product that the product was not intended for the patented indication. Teva (pleading no 7.8 and note 44) rightly points out that the French court in the case did not consider the French equivalent of section 73(1) ROW 1995 applicable. The case was judged on the basis of the French equivalent of Article 73(2) ROW 1995, the rule on commonly marketed products. For an English translation, see www.frenchpatentcaselae.info) and on this ruling, see further Floyd LJ [2016] EWCA Civ 1006, para 193.

51See also R. Kleemans, IEF 16315.

52This is close to the determination of the scope of protection, with apparently this difference [2015] EWCA Civ 556: "117. The distinction in the present case between the technical subject matter for which the patentee seeks protection in the claims and the legal rights which flow from it is perhaps obscured because the word "use" appears both in the claim and in section 60(1)(c). However in the claim ("use ... in the manufacture"), the use is a step in a process, whereas in the statutory provision it is concerned with whether there is use by some person of the process as a whole."

53Which, according to Arnold J, was not the case: the doctor prescribing the substance for pain management does not know which drug the pharmacist will dispense; the pharmacist dispensing a drug does not know for which indication it will be dispensed; and the patient has no relevant intention in this regard. See [2016] EWCA Civ 1006, paras 213-215.

54It is also conceivable that the remedy (injunction, damages) could be tailored to the infringing quantity of products.

55The court judgment in that summary proceedings did not reach the treatment of indirect infringement.

56Bundesgerichtshof 14 June 2016, X ZR 29/15 (Eli Lilly/Actavis), ov. 83-85. Teva (pleading no 7.8 points to this ruling under the name Pemetrexed.

57R.M. Kleemans and J.D. Drok, Interpretation of Swiss-type claims and EPC 2000 claims, IER 2017/3.

58See, however, in the context of validity, TKvB 30 January 2014, T 1780/12 and TKvB 20 October 2015, T 1673/11. Cf. also GKB 19 February 2010, G2/08.

59Dr. J. Bühling, Germany, para. 2.1, in: J. Bühling et al, Patent Protection for Second Medical Uses (AIPPI Law Series 2016).

60Cf. a Madrid Court of Appeal decision of 13 October 2016, case 539/07 (Wyeth v Arafarma and Qualtec) which is cited and quoted in part in Floyd LJ [2016] EWCA Civ 1006, para 192: " (...) the Madrid Court of Appeal considered that it was necessary to show that: "... the defendants have marketed their [drug] by having applied for and received the administrative approval for the same for the new patented therapeutic indication or had perfomed another procedure directed at strengthening the use of the same for that new indication." (emphasis supplied)."

61Cf [2016] EWCA Civ 1006, paras 190-191.

62LG Hamburg Urt. v 2.4.2015 - 327 O 67/15, GRURRS 2015, 8240; see also 327 O 143/15, 315 O 24/15, 327 O 132/15 and 327 O 140/15 (Warner-Lambert/Hexal, 1 A Pharma and Others).

63For more background information on the protection and infringement of second medical indication patents, I refer to J. Bühling et al, Patent Protection for Second Medical Uses (AIPPI Law Series 2016) in which book, among others, discusses the situation in Germany, Switzerland, France, the Netherlands, Italy, Sweden, Denmark, Poland, United Kingdom, Israel, United States of America, Canada, Australia, Japan, Korea, China, India, Brazil and Mexico.

64EP 861 does not include drawings.

65The question of scope of protection and reserved actions should in principle be assessed separately. Cf. HR 5 February 2016, ECLI:NL:HR:2016:196, para 3.38 (Bayer/Sandoz) and A-G Van Peursem's opinion under 2.38 in this case.

66In particular in the text underlined below in claim 1 of EP 861: "The use of ribavirin for the preparation of a pharmaceutical composition for the treatment of a patient with chronic hepatitis C infection, for the destruction of detectable HCV-RNA, where the pharmaceutical composition serves to administer an active amount of ribavirin, together with an active amount of alpha interferon, characterised thereby that the ribavirin, together with the alpha-interferon, is for administration over a period of time of about 40-50 weeks, wherein the patient is a patient naive to anti-viral treatment with HCV genotype 1 infection and a viral load of more than 2 million copies per ml of serum, as determined by HCV-RNA quantitative PCR."

67I also read indirect support for this idea in paragraph 5.1, where the court presumptively assumes a case of direct infringement. Therein, although reference is made to direct infringement of a process claim in the form of the use or marketing of the product obtained directly by the process (Art. 64(2) EPC, Art. 53(1)(b) ROW), but by way of example.

68I also read indirect support for this idea in para 6.1 et seq, where the court presumptively assumes a case of indirect infringement. The court does not discuss the element of science, but concludes in rov. 6.5 that generic ribavirin is not a device concerning an essential element of the invention of EP 861.

69Cf. MSD s.t. no. 80; T.M. Blomme, note under the judgment under appeal, BIE 2015/53 p. 254.

70See also Teva rejoinder no. 2.17.

71See [2015] EWCA Civ 556, para 121: "The prior use of the compound may in fact have produced the effect, for example if a patient taking it for GAD or epilepsy was at the time experiencing pain as well. This demonstrates, to my mind, that it is the intention for which the compound is administered which is at the heart of the invention." and para 125: "the subject matter of the invention is concerned with the purpose of acts which are in themselves no different from those which were done before." See further [2016] EWCA Cic 1006, para 216: "Intentional use is to be distinguished from use where the drug is prescribed for a different indication and, without it in any sense being the intention of the treatment, a pain condition is in fact treated."

72BIE 2015/53 at p. 254; see also R.M. Kleemans & J.D. Drok, Interpretation of Swiss-type claims and EPC 2000 claims, IER 2017/3, footnote 16.

73GKB 19 February 2010, G 2/08.

74See the opinion of A-G Van Peursem for HR 14 April 2017, ECLI:NL:HR:2017:692 (Sun/Novartis) at 2.25-2.26.

75 On the court's interpretation of the case-law of the Bundesgerichtshof, I will not go into further detail here, as section 79(1)(b) of the RO makes it clear that the Supreme Court does not set aside judgments on account of violation of the law of foreign states. In so far as the plea complains about this, it needs no discussion (see in particular parts 3.6-3.9 and 3.11) The same applies to the complaints about Benyamini (parts 3.4-3.5).

76HR 31 October 2003, ECLI:NL:HR:2003:AI0346, NJ 2006/600, BIE 2004/47, cf. J. den Hartog.

77To know that the court's interpretation of the patent is of a factual nature and is subject to only limited review in cassation.

78See the note by J. den Hartog to this judgment (BIE 2004/47) as well as the note by T.M. Blomme under the judgment contested in this case (BIE 2015/53 at p. 254). See also critically W.A. Hoyng, Contributory Infringement', in: D. van Engelen (ed.), On the Brink of European Patent Law, 2011, p. 73.

79MSD s.t. nos 103-104 refers to BGH4 May 2004, X ZR 48/03 (Flügelradzähler) and High Court of Justice 22 April 2013, [2013] EWHC 923 (Pat) (Nestec/Dualit), para 175.

80Ch. Heath, 'Contributory Patent Infringement - Cases of Repair and Refill', in: D. van Engelen (ed.), On the Brink of European Patent Law, 2011, pp. 106-107 and 109 endorses the approach of the Senseo judgment, but considers that the coffee bucket is indeed "essential in the patent sense".

81See in this regard Parliamentary Papers II 1984-1985, 19 131, p. 34: "The means must relate to an essential element of the invention. It is not sufficient that the means can be used in the application of the invention, they must constitute an essential element thereof. On the other hand, it is not necessary for the means to be specially adapted to the invention." Cf. also Hoyng, Repairing in Patent Law (diss. KUB 1988), p. 199-200: "There will only be 'means relating to an essential element of the invention' if the elements belong to the patented combination. However, the word 'concerning' (as well as the French 'se rapportant à' and the English 'relating to') leaves some doubt due to its vagueness."

82HR 13 January 2006, ECLI:NL:HR:2006:AU3256, concerned a case in which the allegedly infringing calling card merely used prior art and was therefore separate from the patented calling card.

83Cf. Arnold J [2015] EWHC 2548 (Pat), para 684: "(...) there is no difficulty in concluding that Lecaent's active ingredient is 'means, relating to an essential element of the invention, for putting the invention into effect' (...)". The Landgericht Hamburg (327 O 143/15, p. 11/22) considered: "Es bedarf keiner näheren Erläuterungen, dass es sich bei der von der Antragsgegnerin hergestellten Zusammensetzung des Präparats der Antragsgegnerin um ein wesentliches Mittel der Erfindung handelt. Es ist zentraler Bestandteil des Patentanspruchs zu 1. Zu dieser Zusammensetzung muss für die Verwirklichung einer unmittelbaren Patentverletzung nur noch die Verwendung für die Indikation "Schmerzen" hinzutreten".

84See the s.t. on behalf of MSD at 151 and the Teva pleading at 6.1.

# Cour de cassation, civile, Chambre commerciale, 8 juin 2017, 15-29.378, Publié au bulletin

#### Cour de cassation - Chambre commerciale

• N° de pourvoi : 15-29.378

• ECLI:FR:CCASS:2017:CO00879

• Publié au bulletin

• Solution : Cassation partielle

Audience publique du jeudi 08 juin 2017

Décision attaquée : Cour d'appel de Paris, du 25 novembre 2014

#### **Président**

Mme Mouillard

#### Avocat(s)

SCP Bénabent et Jéhannin, SCP Hémery et Thomas-Raquin

## Texte intégral

### RÉPUBLIQUE FRANCAISE AU NOM DU PEUPLE FRANCAIS

LA COUR DE CASSATION, CHAMBRE COMMERCIALE, a rendu l'arrêt suivant :

Donne acte aux sociétés Global hygiène et Sipinco du désistement de leur pourvoi incident ;

Attendu, selon l'arrêt attaqué, que la société SCA Tissue France est titulaire du brevet européen EP 1 799 083, désignant la France, ayant pour titre "distributeur de papier toilette dans lequel est logé un rouleau, le rouleau de papier toilette et le distributeur"; que ce brevet couvre, aux termes de sa revendication 1, un distributeur de papier, comprenant un boîtier dans lequel est logé un rouleau d'une bande de papier, qui comprend des prédécoupes transversales à la bande définissant des feuilles de papier rectangulaires, dont la largeur est transversale et la longueur longitudinale, le boîtier comportant un orifice de distribution, par lequel la bande de papier est dévidée, la largeur d'une feuille étant comprise entre 125 mm et 180 mm et le rapport de la largeur d'une feuille sur sa longueur étant compris entre 0,45 et 1, de préférence entre 0,5 et 0,65, caractérisé en ce que ledit papier est un papier

toilette et ledit distributeur comporte une buse avec ledit orifice de distribution, ladite buse et ledit rouleau de papier étant agencés pour que les feuilles de papier se dévident une à une et sortent avec un froissement réduit à la sortie de la buse ; qu'elle a assigné les sociétés Sipinco et Global hygiène en contrefaçon de ce brevet ;

Sur le moyen unique du pourvoi principal, pris en sa première branche :

Vu l'article L. 613-4 du code de la propriété intellectuelle ;

Attendu que pour rejeter les demandes formées par la société SCA Tissue France sur le fondement de la contrefaçon par fourniture de moyens en raison de la mise sur le marché de rouleaux de papier tels que ceux décrits au brevet, l'arrêt énonce que ce dernier couvre une invention de combinaison consistant dans l'association de moyens, papier toilette et buse, que seul l'agencement des moyens coopérant entre eux en vue d'un résultat commun est protégé et qu'en pareil cas, le moyen se rapportant à un élément essentiel de l'invention brevetée ne peut consister dans l'un seulement des éléments combinés, pour le seul motif que ce moyen entre dans la constitution de l'invention et contribue au résultat qu'elle produit;

Qu'en statuant ainsi, alors que la contrefaçon, par fourniture de moyens, d'un brevet couvrant une invention consistant en une combinaison de moyens peut résulter de la fourniture d'un moyen se rapportant à un élément essentiel de celle-ci, lorsque le tiers sait ou lorsque les circonstances rendent évident que ce moyen est apte et destiné à la mise en oeuvre de cette invention, lors même qu'il en est un élément constitutif, la cour d'appel a violé le texte susvisé;

Sur le moyen, pris en sa troisième branche :

Vu l'article L. 613-4 du code de la propriété intellectuelle ;

Attendu que pour statuer ainsi, l'arrêt retient que la seule livraison ou offre de livraison de rouleaux de papier, qui ne sont que des consommables, ne saurait constituer un acte de contrefaçon par fourniture de moyens;

Qu'en statuant ainsi, alors qu'est interdite, à défaut de consentement du propriétaire du brevet, la livraison ou l'offre de livraison, sur le territoire français, à une personne autre que celles habilitées à exploiter l'invention brevetée, des moyens de mise en oeuvre, sur ce territoire, de cette invention se rapportant à un élément essentiel, de sorte qu'il est indifférent que ce moyen puisse consister en un élément consommable, s'il revêt ce caractère essentiel, la cour d'appel a violé le texte susvisé;

Et sur le moyen, pris en sa quatrième branche :

Vu l'article L. 613-4 du code de la propriété intellectuelle ;

Attendu que pour statuer ainsi, l'arrêt retient, enfin, qu'aucun document émanant de la société Sipinco ne fait état d'une compatibilité de ses rouleaux de papier toilette avec les distributeurs commercialisés par la société SCA Tissue France et qu'il n'est pas démontré que la société Global hygiène aurait personnellement fait état d'une telle compatibilité;

Qu'en se déterminant ainsi, alors que dans ses conclusions d'appel, la société SCA Tissue France faisait valoir que, compte tenu de ses dimensions spécifiques, le papier incriminé ne correspondait pas aux papiers toilettes se trouvant couramment dans le commerce, la cour d'appel, qui n'a pas recherché si cette circonstance était établie et, en ce cas, si elle ne devait pas être prise en considération pour examiner si les sociétés Sipinco et Global hygiène savaient, ou si cette circonstance rendait évident, que ces rouleaux étaient aptes et destinés à la mise en oeuvre de l'invention, la cour d'appel n'a pas donné de base légale à sa décision ;

PAR CES MOTIFS, et sans qu'il y ait lieu de statuer sur le dernier grief :

CASSE ET ANNULE, mais seulement en ce qu'il rejette les demandes formées par la société SCA Tissue France au titre de la contrefaçon, par fourniture de moyens, du brevet européen EP 1 799 083, l'arrêt rendu le 25 novembre 2014, entre les parties, par la cour d'appel de Paris ; remet, en conséquence, sur ces points, la cause et les parties dans l'état où elles se trouvaient avant ledit arrêt et, pour être fait droit, les renvoie devant la cour d'appel de Paris, autrement composée ;

Condamne les sociétés Sipinco et Global hygiène aux dépens ;

Vu l'article 700 du code de procédure civile, rejette leur demande et les condamne à payer à la société SCA Tissue France la somme globale de 3 000 euros ;

Dit que sur les diligences du procureur général près la Cour de cassation, le présent arrêt sera transmis pour être transcrit en marge ou à la suite de l'arrêt partiellement cassé;

Ainsi fait et jugé par la Cour de cassation, chambre commerciale, financière et économique, et prononcé par le président en son audience publique du huit juin deux mille dix-sept.

#### REPUBLIQUE FRANÇAISE

AU NOM DU PEUPLE FRANÇAIS

#### **COUR D'APPEL DE PARIS**

#### 4ème Chambre - Section A ARRET DU 04 MARS 2009

Numéro d'inscription au répertoire général : 07/08437

Décision déférée à la Cour : Jugement du 07 Février 2007 -Tribunal de Grande Instance de PARIS-RGn° 05/11023

#### **APPELANTE**

#### Fondation reconnue d'utilité publique INSTITUT PASTEUR,

agissant poursuites et diligences en la personne de ses représentants légaux [...]

**75015 PARIS** 

représentée par la SCP BOMMART-FORSTER - FROMANTIN, avoués à la Cour assistée de Me Marina C, avocat au barreau de PARIS, toque : LO 295

#### **INTIMEES**

# S.A.S. CHIRON HEALTHCARE, nouvelle dénomination de la Société CHIRON BLOOD TESTING SAS.

prise en la personne de ses représentants légaux, lOrueChevreul

92150 SURESNES

représentée par la SCP FISSELIER - CHILOUX - BOULAY, avoués à la Cour assistée de Me B, avocat au barreau de PARIS, toque : P24, Me Pierre V, avocat au barreau de PARIS, toque : P24

#### Société de droit irlandais CHIRON HEALTHCARE IRELAND LIMITED,

prise en la personne de ses représentants légaux United Drug House Belgarde Road

**DUBLIN 24 IRLANDE** 

représentée par la SCP FISSELIER - CHILOUX - BOULAY, avoués à la Cour assistée de Me B, avocat au barreau de PARIS, toque : P24, Me Pierre V, avocat au barreau de PARIS, toque : P24

#### **COMPOSITION DE LA COUR**:

L'affaire a été débattue le 12 Janvier 2009, en audience publique, devant la Cour composée de :

Monsieur Alain CARRE-PIERRAT, Président Madame Dominique ROSENTHAL, Conseiller Mme Brigitte CHOKRON, Conseiller

**GREFFIER** : lors des débats : Mme Jacqueline VIGNAL

#### **ARRET**: CONTRADICTOIRE

- rendu par mise à disposition de l'arrêt au greffe de la Cour, les parties en ayant été préalablement avisées dans les conditions prévues au deuxième alinéa de l'article 450 du nouveau Code de procédure civile.
- signé par Nous, Dominique ROSENTHAL, Conseiller le plus ancien ayant délibéré, en l'empêchement de Monsieur Alain C PIERRAT, président etparNous Jacqueline VIGNAL, greffier à laquelle la minute du présent arrêt a été remise par le magistrat signataire.

Vu l'appel interjeté le 14 mai 2007, par l'INSTITUT PASTEUR d'un jugement rendu le 7 février 2007 par le tribunal de grande instance de Paris qui, le déboutant de ses demandes, l'a condamné à payer aux sociétés CHIRON une indemnité de 45.000 euros au titre de l'article 700 du Code de procédure civile et à supporter les dépens ;

Vu les dernières écritures en date du 17 octobre 2008, par lesquelles l'INSTITUT PASTEUR, poursuivant l'infirmation de la décision entreprise en ce qu'elle n'a pas retenu :

- le caractère pionnier des inventions protégées par le brevet européen EP n° 178978, -que la revendication 11 du brevet européen EP n° 178978 couvre bien l'ARN génomique complet spécifique du virus HIV -1, responsable du SIDA,
- que le grief de contrefaçon de la revendication 11 du brevet européen EP n° 178978 était fondé,
- que la revendication 8 du brevet européen EP n° 178 978 couvre bien le moyen général caractérisé par l'utilisation de l'ARN du virus du SIDA pour la détection de l'infection virale par hybridation ARN viral ADN,
- que le grief de contrefaçon de la revendication 8 du brevet européen EP n° 178978 était fondé,
- \* demande à la Cour, statuant à nouveau, de dire que les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED se sont rendues coupables de contrefaçon des revendications 8 et 11 du brevet n° 178978,
- \* en conséquence, à titre principal :
- \* dire que la revendication 8 est contrefaite par équivalence par les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED , lesquelles offrent en France des tests PROCLEIX reproduisant ladite revendication,
- \* dire que la revendication 8 est aussi contrefaite par la fourniture des moyens permettant la mise en œuvre du procédé couvert par la revendication 8,
- \* dire que la revendication 11 est contrefaite par fourniture de moyens,
- \* à titre subsidiaire :
- \* désigner un expert avec mission de déterminer si :
- les oligonucléotides de capture et les amorces promoteurs fournis par les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED s'hybrident bien à l'ARN viral libéré, lors de la mise en œuvre du test PROCLEIX, dans le but de diagnostiquer l'infection par le virus HIV -1,

- l'ARN isolé et purifié, tel que défini par la revendication 11 opposée, est bien identique à l'ARN viral libéré lors de la mise en œuvre de la capture de cible définie par les tests PROCLEIX,
- \* faire injonction aux sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED de communiquer tous les éléments matériels permettant la poursuite de cette expertise,
- \* faire injonction aux sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED de laisser l'accès à tout type d'appareillage ou de matériel permettant la poursuite de cette expertise,

#### à titre principal,

- \* rejeter la demande reconventionnelle des sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED en appel abusif,
- \* condamner à titre provisionnel les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED au paiement de la somme de 8 millions d'euros,
- \* pour le surplus, désigner un expert, avec pour mission :
- de se faire remettre tous les documents justifiant des offres de ventes et des ventes réalisées en France par les Sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED du test PROCLEDC et du matériel requis pour la mise en œuvre du dit test,
- d'évaluer le préjudice subi en tenant compte des taux pratiqués dans ce domaine de haute technologie,
- \* autoriser la publication *du jugement* à intervenir dans 10 journaux ou périodiques
- de son choix sans que le coût pour l'ensemble des insertions ne dépasse 100.000 euros,
- \* condamner les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED au versement de la somme de 130.000 euros au titre de l'article 700 du Code de procédure civile, ainsi qu'aux dépens de première instance et d'appel;

Vu les dernières écritures en date du 3 décembre 2008, aux termes desquelles les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED prient la Cour de :

- \* à titre principal :
- \* confirmer le jugement du Tribunal de grande instance de Paris du 7 février 2007 en ce qu'il a débouté l'INSTITUT PASTEUR de ses demandes en contrefaçon du brevet d'invention n° 178978, pour les motifs suivants :
- la revendication n° 8 ne peut pas être interprétée comme le prétend l'INSTITUT PASTEUR pour couvrir tout procédé pour la détection *in vitro* d'une infection virale due au virus LAV, comprenant la mise en contact d'un échantillon biologique provenant d'une personne chez laquelle l'infection par le LAV est à dépister et contenant de l'ARN sous une forme apte à l'hybridation, *avec une sonde à ADN, telle que l'une de celles comprises dans la revendication*  $n^{\circ}$  7, dans des conditions hybridantes, et la détection de la sonde hybridée, mais cette revendication ne couvre qu'un procédé de détection utilisant une sonde de la revendication  $n^{\circ}$ 7,
- en conséquence, en important et commercialisant leur kit de diagnostic, les sociétés CHIRON ne fournissent pas les moyens de mise en œuvre de la revendication n°8 du brevet n° 178 978,

- en important et commercialisant leur kit de diagnostic, les sociétés CHIRON ne commettent pas d'actes de contrefaçon par fourniture de moyens de la revendication n° 11, faute pour le kit de diagnostic de se rapporter à un élément de la revendication n° 11,

à titre subsidiaire : s sur la revendication 8 du brevet :

- si la revendication n°8 devait être interprétée comme le prétend l'INSTITUT PASTEUR, pour couvrir un *Procédé de détection in vitro d'une infection virale due au virus LAV comprenant la mise en contact d'un échantillon biologique provenant d'une personne chez laquelle l'infection par le LAV est à dépister et contenant de l'ARN sous une forme apte à l'hybridation [avec toute sonde à ADN] dans des conditions hybridantes et la détection de la sonde hybridée :*
- \* dire que cette revendication est nulle pour défaut de nouveauté ou d'activité inventive,

n sur la revendication 11 du brevet :

- s'il était jugé que la contrefaçon de la revendication n°l 1 peut être réalisée alors même que le kit de détection ne comporte aucun élément de cette revendication :
- \* dire que la revendication n°ll du brevet ne peut être interprétée, comme le prétend l'INSTITUT PASTEUR, pour couvrir tout ARN purifié du virus LAV dont la taille serait supérieure à 9,2 kb et indépendamment de savoir s'il correspond à l'ADN complémentaire contenu dans le X.-J19,
- dire qu'en important et commercialisant leur kit de diagnostic, elles ne fournissent pas les moyens de mise en oeuvre de la revendication n°l 1,
- à titre subsidiaire, si la revendication n°ll devait être interprétée comme le prétend l'INSTITUT PASTEUR, dire que cette revendication est nulle pour défaut de nouveauté,
- \* en tout état de cause :
- \* dire que l'appel interjeté par l'INSTITUT PASTEUR est abusif,
- \* le condamner au paiement de la somme de 200.000 euros à titre de dommages et intérêts pour procédure abusive, de la somme de 300.000 euros au titre de l'article 700 du Code de procédure civile,
- \* le condamner aux entiers dépens ;

#### SUR CE, LA COUR,

Considérant que, pour un exposé complet des faits et de la procédure, il est expressément renvoyé au jugement déféré et aux écritures des parties ; qu'il suffit de rappeler que :

- \*1' INSTITUT PASTEUR est une fondation qui exerce une activité de recherche dans le domaine de la microbiologie,
- \* les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED, de droit américain, qui sont spécialisées dans le domaine de la biotechnologie, fabriquent, commercialisent des vaccins, des produits thérapeutiques et des outils de diagnostic sanguin,
- \* au cours des années 1980, plusieurs organismes de recherche ont travaillé à l'identification du virus du sida, notamment le CNRS et l'INSTITUT PASTEUR dirigé par le professeur M, le NIH dépendant du ministère de la santé des Etats Unis dirigé par le professeur G ALLO, le groupe CHIRON sur la base des travaux du professeur L de l'université de San Francisco.

- \* ces organismes ont isolé, en 1984, ce virus, le professeur M l'appelant LAV (lymphadenopathy associated virus), le professeur G le baptisant HTLV-III (human T-cell lymphotropic virus III), le professeur L lui donnant le nom de ARV (aids-associated retroviruses),
- \* ce virus a reçu en 1986, le nom de VIH,
- \* à la suite de ces découvertes, les divers organismes de recherche ont déposé différents brevets pour protéger les parties du génome du VIH identifiées et leur utilisation, notamment à des fins de dépistage du virus :
- un brevet européen n°0173529 déposé par le NIH le 19 août 1985, sous priorité d'une demande de brevet américain n°643306 du 22 août 2004,
- un brevet européen déposé par l'INSTITUT PASTEUR le 17 septembre 1985, sous priorité d'un brevet britannique GB 8423659 du 19 septembre 1984, délivré le 6 février 1991, sous le n° 178978, ayant pour titre séquences d'ADN clonées, hybridisables avec l'ARNgénomique du "lymphadenopathy-associated virus (LAV),
- un brevet européen n°0181150 déposé par la société CHIRON CORPORATION le 30 octobre 1985, sous priorité des demandes de brevets américains n°667501 du 31 octobre 1984, n°696534 du 30 janvier 1985,
- \* des fragments d'ADN correspondant aux clones du VIH séquences et décrits dans ces brevets ont été déposés dans des collections, en application du traité de Budapest : des clones BH10, BH5, BH8 le 30 juillet 1984 par le NIH, des clones X-J19 et X-J81 par l'INSTITUT PASTEUR le 11 septembre 1984, des clones X,-ARV-2 par la société CHIRON CORPORATION le 26 octobre 1984.
- \* reprochant aux sociétés du groupe CHIRON de commercialiser depuis le mois de septembre 1999, des kits de dépistage du VIH sous la dénomination PROCLEIX, constituant, selon lui, les moyens de mise en oeuvre des revendications 8 et 11 de son brevet, dûment autorisé par ordonnance présidentielle, l'INSTITUT PASTEUR a fait procéder à une saisie contrefaçon le 12 juillet 2005,
- \* c' est dans ces circonstances, que l'INSTITUT PASTEUR a assigné les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED devant le tribunal de grande instance de Paris en contrefaçon;

#### Sur le brevet :

Considérant que le brevet européen n°018978, déposé le 17 septembre 1985 par l'INSTITUT PASTEUR, sous priorité britannique du 19 septembre 1984, délivré le 6 février 1991, a fait l'objet d'une procédure d'opposition devant l'Office Européen des Brevets (OEB) par la société CHIRON CORPORATION et a été maintenu avec des revendications modifiées, par décision de la Chambre de recours du 18 novembre 1999 ;

Que l'invention, qui a pour titre séquences d'ADN clonées, hybridisables avec l'ARNgénomique du "lymphadenopathy-associated virus (LA V), porte sur des séquences d'ADN clonées, capables de s'hybrider avec les ARN et ADN génomiques du virus de la lymphadénopathie (LAV), sur un procédé de préparation desdites séquences et sur leurs utilisations, plus particulièrement, sur des sondes stables comprenant des virus apparentés ou des provirus à ADN dans n'importe quel milieu, en particulier dans des échantillons biologiques contenant l'un quelconque d'entre eux ;

Que le breveté rappelle que des virus analogues au LAV ont été isolés à partir de patients atteints du SIDA et pré-SIDA, que ces virus, appelés HTLV-III et ARV séquences d'ADN clonées, hybridisables avec l'ARN génomique du lymphadenopathy-associated virus

(LA V) et ARV, présentent de nombreuses caractéristiques analogues à celles du LAV et représentent des isolats indépendants du prototype de LAV et que par commodité de langage, ils seront tous appelés LAV ;

Qu'il expose que les méthodes de détection disponibles à ce jour sont basées sur la reconnaissance de protéines virales, qu'une méthode de ce type est décrite dans la demande de brevet européen EP- A-013 8667, intitulée *antigènes, moyens et méthode pour le diagnostic de lymphadénopathie et du syndrome d'immunodépression acquise,* déposée le 14 septembre 1984, sous la priorité de la demande de brevet n°8324800 déposée le 15 septembre 1983, que cette demande européenne décrit des clones recombinants du HTLV-III différents ;

Qu'il fait valoir que l'invention vise à proposer de nouveaux moyens qui devraient, non seulement être utiles pour la détection du LAV ou des virus apparentés mais encore présenter plus de souplesse, en particulier dans la détection spécifique de l'ADN génomique desdits virus, dont les produits d'expression ne sont pas toujours détectables par des méthodes immunologiques ;

Que le brevet comporte 11 revendications ainsi libellées :

Revendication 1 : ADN clone contenant un ADN correspondant au génome rétroviral du virus de la lymphadénopathie (LAV) et contenu dans le ÀJJ9 (CNCM1-338), cet ADN clone comportant les éléments U3, R et U5 de ce génome rétroviral,

Revendication 2: ADN selon la revendication 1 qui est un ADNc,

Revendication 3 : ADN clone contenant un ADN qui consiste :

- en un fragment de l'extrémité 3' de l'ADN contenu dans le U19 (CNCM 1-338) correspondant au génome rètroviral du LAVet ayant jusqu 'à 2,5 kb contenant les sites de restriction suivants, dans les ordres respectifs suivants (de l'extrémité 3'àl 'extrémité 5') :
- 1) soit Hind III, Sac I, Bgl II,
- 2) soit Hind III, Sac I, Bgl II, Bgl II, Kpn I,
- 3) soit Hind III, Sac I, Bgl II, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II,

Revendication 4 : un fragment clone dont la séquence correspond à la partie de l'ADN de U19 qui s'étend approximativement du site Kpn I (6100) jusqu 'au site Bam HI (8150) approximativement,

Revendication 5 : un fragment d'ADN clone dont la séquence correspond à la partie de l'ADN deXJ19 qui s'étend approximativement du site Kpn I (3500) jusqu 'au site Bgl II (6500) approximativement,

Revendication 6 : un fragment d'ADN dont la séquence correspond à la partie de l'ADN de U19 qui s'étend approximativement du site Pst (800) jusqu'au site Kpn I (3500) approximativement,

Revendication 7 : sonde pour la détection in vitro du LA V en un ADN selon l'une quelconque des revendications 1 à 6,

Revendication 8 : procédé pour la détection in vitro d'une infection virale due aux virus LAV, comprenant la mise en contact d'un échantillon biologique provenant d'une personne chez laquelle l'infectionpar le LA Vest à dépister et contenant de l'ARNsous une forme apte à

l'hybridation avec la sonde de la revendication 7 dans des conditions hybridantes, et la détection de la sonde hybridée,

Revendication 9 : vecteur, plus particulièrement un plasmide, pour la transformation de cellules eucaryotes ou procaryotes, contenant un fragment d'insertion selon l'une quelconque des revendications 1 à 6.

Revendication 10 : microorganisme, cellule procaryote ou eucaryote, transformé par un vecteur selon la revendication 9.

Revendication 11 : ARNpurifié du virus LAV ayant une taille de 9.1 à 9.2 kb et correspondant à l'ADN complémentaire contenu dans le }J19 (CNCM 1-338);

Considérant que l'INSTITUT PASTEUR oppose les revendications 8 et 11 de ce document :

#### Sur la portée des revendications 8 et 11 du brevet :

Considérant que l'INSTITUT PASTEUR soutient que le test PROCLEDC argué de contrefaçon fournit, au sens de l'article L.613-4 du Code de la propriété intellectuelle, tous les moyens de mise en oeuvre permettant l'isolement de l'ARN couvert par la revendication 11, avant de fournir ceux du procédé rendant possible la détection in vitro d'une infection virale due au virus LAV ou HIV-I couverts par la revendication 8 du dit brevet ;

Que de sorte, exposant que la caractérisation et la possibilité d'utiliser le génome ARN du virus responsable du SIDA est un préalable à la mise en oeuvre du procédé de diagnostic couvert par la revendication 8 du brevet, l'INSTITUT PASTEUR oppose en premier lieu la revendication 11 qui protège l'ARN purifié du virus ayant une taille de 9,1 à 9,2 kb et correspondant à l'ADN complémentaire contenu dans le À, J19 (CNCM1-338);

Considérant que les parties s'opposent sur la portée des revendications 8 et 11 du brevet ;

Considérant en droit que selon l'article 69 de la Convention de Munich / 'étendue de la protection conférée par le brevet européen ou par la demande de brevet est déterminée par la teneur des revendications, toutefois la description et les dessins servent à interpréter les revendications ;

Considérant que l'INSTITUT PASTEUR soutient que le brevet n°178978 constitue une innovation de premier ordre qui en fait un brevet pionnier, de sorte que, selon lui, les revendications 8 et 11 ont une portée allant au-delà de leur sens littéral;

Mais considérant que si en présence d'une invention pionnière, le brevet peut décrire un mode de réalisation de l'invention et revendiquer tout autre mode de réalisation possible, en revanche, même un brevet pionnier ne peut se voir accorder une portée générale si ses revendications sont rédigées en termes restrictifs,

Qu'une revendication non ambiguë, de portée étroite, ne saurait se voir accorder, sous couvert d'une interprétation, une portée générale, lorsque, notamment le breveté a été contraint de limiter la portée de la revendication dans le cadre de procédures de délivrance et d'opposition pour se distinguer de l'art antérieur ;

Or, considérant qu'en l'espèce il est établi que la demande de brevet a été déposée initialement avec 24 revendications et que, par suite de la procédure d'opposition engagée par la société CHIRON CORPORATION, qui a donné lieu à une décision de première instance le 9 août 1994, puis, en appel, à une décision de la Chambre des recours de l'OEB le 18 novembre 1994, le brevet délivré comporte 11 revendications **d'une portée réduite**;

#### <u>Sur la revendication 11</u>:

Considérant que la revendication 11 telle que déposée portait sur *Les ARN purifiés des virus LA V ayant une taille de 9,1 à 9,2 kb* ; que modifiée, elle protège / 'ARN purifié du virus LAV ayant une taille de 9.1 à 9.2 kb et correspondant à l'ADN complémentaire contenu dans le XJ19 (CNCM 1-338) ;

Considérant que l'INSTITUT PASTEUR, exposant qu'aucun document de l'art antérieur ne justifie une lecture stricte de cette revendication, prétend néanmoins qu'elle protège, indépendamment du clone X- J19, caractère spécifique de la séquence revendiquée, la totalité du génome d'ARN purifié du virus LAV ou HIV-1, composé indispensable à la mise en oeuvre du protocole de détection de la présence du virus dans un échantillon biologique à tester ;

Mais considérant que le breveté qui a modifié ses revendications pour leur donner une portée restreinte, ne peut, sans porter atteinte à la sécurité des tiers, prétendre que les modifications n'étaient pas nécessaires, que les revendications restreintes auraient la même portée que celles d'origine plus larges et que les documents de l'art antérieur ayant motivé les modifications ne seraient pas pertinents ;

Considérant que l'INSTITUT PASTEUR soutient que l'ADN complémentaire (ADNc) auquel la revendication 11 fait référence correspond à l'image dans un miroir du génome de l'ARN du virus LAV (ou HIV-1) et ne se confond pas avec l'ADN proviral décrit dans la demande de brevet américain n°0173529 déposée le 22 août 1984, par le

Considérant que s'il n'est pas contesté que les clones décrits dans ces documents ont été obtenus de façons différentes, il n'en demeure pas moins que, dans les deux cas, le clone obtenu et décrit est composé de l'ADN double brin correspondant au génome viral duVIH;

Que dans ces circonstances, le brevet NIH, qui divulgue les sites de restriction de l'ADN du VIH, antériorise en partie le brevet de l'INSTITUT PASTEUR, peu important la suggestion de la présence d'un gène pX, qui n'appartient pas au génome du VIH;

Considérant par ailleurs, que le 31 août 1984, les chercheurs de l'équipe du professeur G ont publié le résultat de leurs recherches dans la revue SCIENCE ;

Que cet article dénommé ARYA, G divulgue une méthode générale permettant de purifier l'ARN du VIH, provenant du sang d'un patient atteint du sida et enseigne que les brins d'ARN isolés, qui ont une taille d'environ 9 kb, comportent l'intégralité de la région R à chaque queue polyA;

Considérant qu'il résulte de ce qui précède, que la seule caractéristique permettant de distinguer la revendication 11 litigieuse est le caractère spécifique du brin revendiqué, à savoir sa taille d'approximativement 9,1 à 9,2 kb et sa capacité à s 'hybrider avec l'ADNc contenu dans le clone X.-J19;

#### <u>Sur la revendication 8</u>:

Considérant que l'INSTITUT PASTEUR soutient que la revendication 8 du brevet porte sur un procédé pour détecter in vitro une infection virale due au virus LAV qui suppose la mise en contact d'un échantillon biologique provenant d'un patient suspecté d'être infecté par le LAV (HIV-I), ledit échantillon contenant de l'ARN sous une forme permettant l'hybridation avec la sonde de la revendication 7 dans des conditions hybridantes et permettant la détection de la sonde hybridée ;

Qu'il prétend que le procédé couvert par cette revendication protège un moyen général nouveau permettant la détection de la charge virale du sida caractérisé par l'hybridation de sondes d'ADN à l'ARN viral et qu'il ne peut se voir limiter par le choix de la sonde selon la revendication 7;

Considérant que, rappelant l'énoncé de la revendication 8 ainsi libellée : procédé pour la détection in vitro d'une infection virale due aux virus LA V, comprenant la mise en contact d'un échantillon biologique provenant d'unepersonne chez laquelle l'infection par le LA V est à dépister et contenant de l'ARN sous une forme apte à l'hybridation avec la sonde de la revendication 7 dans des conditions hybridantes, et la détection de la sonde hybridée, il convient de relever que le procédé comporte deux étapes : d'une part, la mise en contact, dans des conditions hybridantes d'un échantillon biologique provenant d'une personne infectée par le LAV et contenant de l'ARN sous une forme apte à l'hybridation, avec la sonde de la revendication 7 et d'autre part, la détection de la sonde hybridée;

Que force est de constater que les modifications, qui ont été apportées par l'INSTITUT PASTEUR lors de la procédure d'examen, ont eu pour conséquence de limiter la portée de la revendication 8 en ce qu'elle requiert l'utilisation de la sonde objet de la revendication 7, dépendante des revendications 1 à 6 protégeant des fragments d'ADN clones définis à celles-ci par leurs sites de restriction et correspondant au génome rétro viral contenu dans le clone À-J19;

Que cette interprétation est confirmée par la description qui renvoie (page 17, ligne 27 et suivantes, page 18, lignes 10 et suivantes) à des fragments d'ADN conformes à l'invention et ne décrit pas le moyen général de sondes ;

Qu'il appartenait à l'INSTITUT PASTEUR, lors de la procédure d'examen et d'opposition de modifier la revendication de procédé ou les revendications de sonde pour les dissocier des revendications de fragments ;

Que l'INSTITUT PASTEUR ne saurait soutenir que la revendication 8 couvrirait toute méthode de diagnostic, quelle que soit la sonde utilisée, au motif invoqué que cette revendication renverrait indirectement à la revendication 1, laquelle, du fait de l'utilisation du terme "correspondant", continuerait à couvrir n'importe quel fragment d'ADN;

Qu'en effet, la Chambre des recours de l'OEB, au sujet de la revendication 1, a rappelé que le vocable "correspondant" semble être employé dans le sens restreint d'une stricte correspondance, de base à base, soumise à des variations admissibles qui ne modifieraient pas de façon considérable leur capacité d'hybridation avec les génomes rétroviraux de LA V, comme l'homme du métier le comprendrait;

Que de sorte, sans dénaturer cette décision, il ne saurait être prétendu que la protection des variations admissibles s'étendrait également à la protection de tous les fragments d'ADN équivalents ;

Qu'il s'ensuit, étant, au besoin, rappelé que l'article publié par les chercheurs du NIH : ARYA, G ALLO, antérieurement à la date de priorité du brevet, enseignait déjà la détection d'une infection due au VIH par l'utilisation de sondes marquées, que la revendication 1 couvrant 1 'ADN clone contenu dans le *X-i* 19 et tout ADN clone identique, ne protège nullement tout fragment de l'ADN, de sorte, que la revendication 8 ne saurait porter sur toute méthode de diagnostic indépendamment du type de sonde utilisé ;

Considérant par voie de conséquence, que la portée de la revendication 8 est limitée à un procédé de détection impliquant l'utilisation de sondes composées des fragments clones et comportant un fragment d'ADN correspondant au génome rétro viral contenu dans le A.-J19;

Considérant que la portée des revendications 8 et 11 du brevet opposé étant ainsi définie, il n'y pas lieu d'examiner la demande subsidiaire en nullité de ces revendications formée par les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED qui ne contestent pas leur validité telles que modifiées après opposition et telles qu'interprétées ;

#### Sur la contrefaçon des revendications 8 et 11 :

Considérant que l'INSTITUT PASTEUR, qui reproche aux sociétés CHIRON des actes de contrefaçon, expose que le test PROCLEIX incriminé, qui comporte trois étapes (une étape d'isolement de l'ARN viral, une étape d'amplification de l'ARN viral et **une** étape de détection des produits résultant de cette amplification), fournit les moyens de mise en oeuvre par équivalence des revendications 8 et 11 du brevet opposé;

Considérant en droit que selon les dispositions de l'article L.613-4 du Code de la propriété intellectuelle, est interdite, à défaut de consentement du propriétaire du brevet, la livraison ou l'offre à la livraison, sur le territoire français, à une personne autre que celles habilitées à exploiter l'invention brevetée, des moyens de mise en oeuvre, sur ce territoire, de cette invention se rapportant à un élément essentiel de celle-ci, lorsque le tiers sait ou lorsque les circonstances rendent évident que ces moyens sont aptes et destinés à cette mise en oeuvre;

Considérant que l'INSTITUT PASTEUR ne dément pas les explications des sociétés CHIRON sur le procédé de mise en oeuvre de ce kit, à savoir :

- la capture des ARN cibles consistant à libérer les ARN viraux par lyse cellulaire, capturer les ARN viraux à l'aide d'oligonucléotides de capture venant s'hybrider aux ARN cibles et s'attacher à des micro-particules magnétiques,
- le lavage destiné à éliminer les composants plasmatiques et les acides nucléotiques autres que eeux fixés aux oligonucléotides de capture, étant précisé que ces oligonucléotides de capture sont des séquences synthétiques composés pour partie d'ADN et d'ARN,
- une étape d'amplification mettant en oeuvre les amorces d'amplification, en utilisant deux amorces constituées d'oligonucléotides synthétiques dont la fonction est de démarrer des étapes de transcription inverse et de polymérase, l'amorce promoteur incluant une zone dénommée "promoteur 7" nécessaire à la fonction de polymérase ARN,

- une étape de détection consistant à hybrider l'ARN amplifié à des sondes marquées par une substance luminescente, deux sondes virales, une sonde de contrôle interne, constituées d'oligonucléotides synthétiques, de très faible longueur (inférieure à 25 nucléotides chacune) et non contiguës, placées en plusieurs endroits du génome,
- une phase d'incubation au cours de laquelle les sondes viennent s'hybrider avec l'ARN antisens amplifié,
- l'ARN viral capturé est le génome viral complet, comprenant l'intégralité de la région R à chaque extrémité, auquel est jointe la queue polyA, ARN isolé et décrit dans l'article ARYA, G précité ;

#### Sur la revendication 8:

Considérant que le kit de détection incriminé utilise trois types d'oligonucléotides capables de s'hybrider à du matériel génétique : les oligonucléotides de capture, deux amorces lors de l'étape d'amplification, deux sondes marquées lors de l'étape de détection ;

Considérant que l'INSTITUT PASTEUR allègue que les oligonucléotides de capture et les amorces promoteurs constitueraient des moyens de mise en oeuvre de la revendication 8, qui couvre, selon lui, un moyen général nouveau consistant à l'utilisation de sondes d'ADN capables de s'hybrider à l'ARN génomique pour la détection de l'infection virale par hybridation ARN viral-ADN ;

Qu'il ajoute que ces oligonucléotides et ces amorces sont des moyens équivalents des sondes visées à la revendication opposée ;

Mais considérant, qu'il résulte de ce qui précède que la portée de la revendication 8 est limitée à un procédé de détection impliquant l'utilisation de la sonde objet de la revendication 7, dépendante des revendications 1 à 6 protégeant des fragments d'ADN clones définis par leurs sites de restriction et correspondant au génome rétroviral contenu dans le clone 3C-J19;

Que force est de constater qu'il n'est nullement soutenu par l'INSTITUT PASTEUR que le kit de dépistage des sociétés CHIRON utiliserait les sondes de la revendication 7, composées des fragments des revendications 1 à 6;

Que l'INSTITUT PASTEUR ne démontre pas davantage la reproduction des autres caractéristiques de la revendication 8 ;

Qu'en effet, les oligonucléotides de capture et les amorces des kits de détection de sociétés CHIRON sont synthétiques, de sorte qu'elle ne peuvent entrer dans le champ du brevet qui enseigne des fragments d'ADN clones ;

Que ces oligonucléotides ne sont pas des sondes d'ADN mais sont des oligonucléotides chimères composés pour partie d'ADN et pour partie d'ARN, la partie venant s'hybrider avec l'ARN du VIH étant composé d'ARN, ce qui ne peut être obtenu que par synthèse chimique et non par clonage ;

Que les amorces promoteurs ne constituent pas davantage des sondes de la revendication 8, dès lors qu'elles comportent une zone promoteur "T7", nécessaire à la fonction de polymérase ARN, absente du génome rétroviral contenu dans le X-J19;

Considérant que l'INSTITUT PASTEUR ne saurait recourir à la théorie de 1 'équivalence, alors que la revendication 8 ne couvre pas le moyen général de l'hybridation mais le moyen particulier de l'hybridation de l'ARN viral avec une sonde constituée d'un fragment d'ADN correspondant au génome contenu dans le clone X.-J19 ;

Considérant par voie de conséquence, que la décision déférée, qui a rejeté le grief de contrefaçon de la revendication 8, sera confirmée,

#### <u>Sur la revendication 11</u>:

Considérant que l'INSTITUT PASTEUR soutient que le test de diagnostic des sociétés CHIRON contreferait, par fourniture de moyens, la revendication 11, dès lors, selon elle, que l'utilisation de ce test aboutit à l'isolation de l'ARN du VIH-1;

Considérant que la fourniture de moyens ne constitue un acte de contrefaçon qu'à la condition que les moyens fournis se rapportent à un élément essentiel de l'invention, à savoir, participer à son résultat ;

Qu' en 1 'espèce, force est de constater que la revendication 11 du brevet, telle que modifiée, se rapporte à l'ARN purifié du virus LAV ayant une taille de 9,1 à 9,2 kb et correspondant à l'ADN complémentaire contenu dans le ^-J19 ;

Considérant d'une part, que cette revendication ne couvre pas un procédé mais un produit ; que d'autre part, elle ne caractérise pas l'ARN par le fait qu'il contient toute l'information génétique nécessaire à la reconstitution du génome **complet mais** en **ce** qu'elle définit l'ARN qui correspond à l'ADNc du X-J19 ;

Qu'il n'est nullement démontré que la mise en oeuvre de ce kit permettrait d'isoler précisément le fragment d'ARN correspondant à l'ADN complémentaire contenu dansle A.-J19;

Qu'il n'est pas démenti que l'ARN isolé par les kits des sociétés CHIRON a une taille supérieure à 9,2 kb et contient une séquence R complète à chacune de ses extrémités, de sorte qu'il n'entre pas dans le champ de la revendication 11;

Considérant par voie de conséquence, que la décision déférée, **qui a débouté** l'INSTITUT PASTEUR de ses demandes au titre de la contrefaçon, mérite confirmation ;

#### Sur les autres demandes :

Considérant que l'action en justice, comme l'exercice du droit d'appel, ne dégénère en abus pouvant donner naissance à une dette de dommages et intérêts que dans le cas de malice, de mauvaise foi, d'erreur grossière équipollente au dol ou encore de légèreté blâmable ; que ces exigences ne sont pas satisfaites en l'espèce ; que la demande reconventionnelle formée par les sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED sera rejetée ;

Considérant qu'il ressort du sens de l'arrêt que l'INSTITUT PASTEUR ne saurait bénéficier des dispositions de l'article 700 du Code de procédure civile ; qu'en revanche, l'équité commande de le condamner, sur ce même fondement, à verser aux sociétés CHIRON

HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED la somme complémentaire de 130.000 euros ;

#### **PAR CES MOTIFS**

Confirme en toutes ses dispositions le jugement déféré, Y ajoutant,

Condamne l'INSTITUT PASTEUR à payer aux sociétés CHIRON HEALTHCARE SAS et CHIRON HEALTHCARE IRELAND LIMITED la somme complémentaire de 130.000 euros au titre des frais irrépétibles d'appel,

Rejette toutes autres demandes,

Condamne l'INSTITUT PASTEUR aux dépens et dit que ceux-ci pourront être recouvrés conformément aux dispositions de l'article 699 du Code de procédure civile.

Copies handed down to the parties on:

# FRENCH REPUBLIC IN THE NAME OF THE FRENCH PEOPLE





#### COUR D'APPEL OF PARIS

4th Chamber - Section A

#### **DECISION OF 4 MARCH 2009**

(No. , 12 pages)

Docket number: 07/08437

Decision referred to the Cour d'Appel: Judgment of 7 February 2007 - Tribunal de Grande Instance of PARIS - docket No.: 05/11023

#### **APPELLANT**

#### INSTITUT PASTEUR, a foundation recognized as a public utility

represented by its legal representatives
25-28 rue du Docteur Roux
75015 PARIS
represented by SCP BOMMART - FORSTER - FROMANTIN, avoués
assisted by Ms. Marina COUSTE, attorney-at-law, member of the PARIS Bar, court box: LO 295

#### RESPONDENTS

#### S.A.S. CHIRON HEALTHCARE, formerly known as CHIRON BLOOD TESTING S.A.S.

represented by its legal representatives,

10 rue Chevreul

92150 SURESNES

represented by S.C.P. FISSELIER - CHILOUX - BOULAY, avoués

assisted by Mr. BOUVET, attorney-at-law, member of the PARIS Bar, court box: P24, Mr. Pierre VERON, attorney-at-law, member of the PARIS Bar, court box: P24

#### CHIRON HEALTHCARE IRELAND LIMITED, a company governed by the laws of Ireland

represented by its legal representatives,

United Drug House Belgard Road

**DUBLIN 24 IRELAND** 

represented by S.C.P. FISSELIER - CHILOUX - BOULAY, avoués

assisted by Mr. BOUVET, attorney-at-law, member of the PARIS Bar, court box: P24, Mr. Pierre VERON, attorney-at-law, member of the PARIS Bar, court box: P24

#### **COMPOSITION OF THE COURT**

The case was discussed on 12 January 2009, in public, before the Cour d'Appel composed of:

Mr. Alain CARRE-PIERRAT, Presiding Judge

Ms. Dominique ROSENTHAL, Judge

Ms. Brigitte CHOKRON, Judge

who deliberated

**CLERK:** during the trial: Ms. Jacqueline VIGNAL

#### **DECISION: AFTER HEARING BOTH PARTIES**

- pronounced and filed with the clerk's office, after informing the parties pursuant to the provisions of Article 450, second paragraph, of the New French Code of Civil Procedure.
- signed by Dominique ROSENTHAL, the most senior Judge who deliberated, due to the impediment of Mr. Alain CARRE PIERRAT, Presiding Judge and by Jacqueline VIGNAL, the clerk to whom the signatory judge handed over the true copy of the present decision.

Considering the appeal lodged on 14 May 2007 by INSTITUT PASTEUR against a judgment handed down on 7 February 2007 by the *Tribunal de Grande Instance* of Paris which, dismissing its claims, ordered it to pay CHIRON compensation of 45,000 euros pursuant to Article 700 of the French Code of Civil Procedure and to pay the costs;

Considering the last pleadings dated 17 October 2008, by way of which INSTITUT PASTEUR, seeking the reversal of the appealed judgment in that it did not consider:

- the pioneer nature of the inventions protected by European patent No. 0 178 978,
- that claim 11 of European patent No. 0 178 978 covers the whole specific genomic RNA of HIV-1, causing AIDS,
- that the charge for infringement of claim 11 of European patent No. 0 178 978 was well-founded,
- that claim 8 of European patent No. 0 178 978 covers the general means characterized by the use of the RNA of the AIDS virus for detecting the viral infection by a viral RNA DNA hybridization;
- that the charge for infringement of claim 8 of European patent No. 178 978 was well-founded,
- requests the *Cour d'Appel*, ruling on again, to hold that CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED are liable for infringement of claims 8 and 11 of European patent No. 0 178 978;
- consequently, as main request:
- \* to hold that claim 8 is infringed by equivalence by CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED, which offer in France PROCLEIX assays implementing said claim.
- \* to hold that claim 8 is also infringed by the supply of means for implementing the method covered by claim 8,
- \* to hold that claim 11 is infringed by supply of means,
- in the alternative:
- \* to appoint an expert in charge of determining if:
- the capture oligonucleotides and the promoter primers supplied by CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED hybridize with the released viral RNA, during the implementation of the PROCLEIX assay, for diagnosing the infection by HIV-1,
- the isolated and purified RNA, as defined in the asserted claim 11, is identical to the viral RNA released during the implementation of the target capture defined by the PROCLEIX assays,

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A DECISION OF 4 MARCH 2009 Docket No.: 2007/8437 – 2<sup>th</sup> page

- \* to order CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED to exhibit all the material elements for the performance of these expert investigations,
- \* to order CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED to leave access to any type of equipment or material for the performance of these expert investigations,
- as main request,
- \* to dismiss the counterclaim lodged by CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED for abusive appeal,
- \* to order CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED to pay, as an advance payment, 8 million euros,
- \* for the total compensation, to appoint any expert with a mission:
- being provided with all the documents justifying the offers for sale and sales recorded in France by CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED regarding the PROCLEIX assay and the equipment required for implementing said assay,
- assessing the damage suffered by taking into account the royalty rates applied in this high technology field,
- \* to authorize the publication of the judgment to be handed down in 10 newspapers or magazines at INSTITUT PASTEUR's choice without the cost for all the insertions exceeding 100,000 euros,
- \* to order CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED to pay 130,000 euros pursuant to Article 700 of the French Code of Civil Procedure and to pay the costs of first instance and appeal proceedings;

Considering the last pleadings dated 3 December 2008, in which CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED request the *Cour d'Appel*:

- as main request:
- \* to affirm the judgment of the *Tribunal de Grande Instance* of Paris of 7 February 2007 in that it dismissed INSTITUT PASTEUR's claims for infringement of patent No. 0 178 978 on the following grounds:
- claim 8 cannot be construed, as alleged by INSTITUT PASTEUR, as to cover any method for the *in vitro* detection of viral infection due to the LAV virus which comprises contacting a biological sample originating from a person to be diagnosed for LAV infection and containing RNA in a form suitable for hybridization, with a DNA probe, such as one of those contained in claim 7, under hybridizing conditions and detecting the hybridized probe; this claim however covers only a method for detection using a probe according to claim 7,
- therefore, by importing and marketing their diagnostic kit, CHIRON do not provide the means for implementing claim 8 of patent No. 0 178 978,
- by importing and marketing their diagnostic kit, CHIRON do not infringe claim 11 on the grounds of supply of means, since the diagnostic kit does not relate to an element of claim 11,
- in the alternative:
- a on patent claim 8:
- should claim 8 be construed, as alleged by INSTITUT PASTEUR, to cover a method for the in vitro detection of viral infection due to the LAV virus which comprises contacting a biological sample originating from a person to be diagnosed for LAV infection and containing RNA in a form suitable for hybridization [with any type of DNA probe], under hybridizing conditions and detecting the hybridized probe:

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A DECISION OF 4 MARCH 2009 Docket No.: 2007/8437 – 3<sup>th</sup> page \*hold that this claim is invalid for lack of novelty or inventive step,

pon patent claim 11:

- should it be held that claim I l can be infringed even if the detection kit does not include any element of this claim:
- \* to hold that patent claim 11 cannot be construed, as alleged by INSTITUT PASTEUR, to cover any purified RNA of LAV virus which size would be superior to 9.2 kb and independently to know if it corresponds to the complementary DNA contained in  $\lambda$ -J19,
- to hold that by importing and marketing their diagnostic kit, they do not supply the means for implementing claim 11,
- in the alternative, should claim 11 be construed as alleged by INSTITUT PASTEUR, to hold that this claim is invalid for lack of novelty,
- in any case:
- \* to hold that the appeal lodged by INSTITUT PASTEUR is abusive,
- \* to order INSTITUT PASTEUR to pay a sum of 200,000 euros as damages for abusive proceedings, a sum of 300,000 euros pursuant to Article 700 of the French Code of Civil Procedure,
- \* to order INSTITUT PASTEUR to pay all the costs;

#### WHEREUPON, THE COUR D'APPEL,

Considering that, for a thorough presentation of the facts and of the proceedings, it is expressly referred to the appealed judgment and to the parties' pleadings; that it is sufficient to recall that:

- \* INSTITUT PASTEUR is a foundation involved in research in microbiology,
- \* CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED, companies governed by the laws of the United States, which specialize in biotechnology, manufacture and market vaccines, therapeutic products and blood diagnostic tools,
- \* in the eighties, several public research organizations worked on the identification of the AIDS virus, notably the CNRS and INSTITUT PASTEUR directed by Professor MONTAGNIER, the NIH which depends on the United States Department of Health, directed by Professor GALLO, the group CHIRON on the basis of the work of Professor LEVY of the university of San Francisco,
- \* in 1984, these organizations isolated this virus which was called LAV (Lymphadenopathy Associated Virus) by Professor MONTAGNIER, HTLV-III (Human T-cell Lymphotropic Virus-III) by Professor GALLO and ARV (AIDS-Associated Retroviruses) by Professor LEVY,
- \* this virus was called HIV in 1986,
- \* following these discoveries, the various research organizations filed different patents to protect the identified parts of the HIV genome as well as their use, in particular for the detection of the virus:
- European patent No. 0 173 529 filed by the NIH on 19 August 1985 under the priority of a US patent application No. 643,306 dated 22 August 1984<sup>1</sup>,
- European patent filed by INSTITUT PASTEUR on 17 September 1985 under the priority of a British patent No. 8423659 dated 19 September 1984, granted on 6 February 1991 under No. 0 178 978, entitled Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV),
- European patent No. 0 181 150 filed by CHIRON CORPORATION on 30 October 1985 under the priority of US patent applications No. 667,501 of 31 October 1984, No. 696,534 of 30 January 1985,
- \* DNA fragments corresponding to the HIV clones sequenced and described in these patents were deposited in collections pursuant to the Budapest Treaty:

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A

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<sup>&</sup>lt;sup>1</sup> Translator's note: 2004 in the French text

clones called BH10, BH5 and BH8 were deposited by the NIH on 30 July 1984; clones  $\lambda$ -J19 and  $\lambda$ -J81 were deposited by INSTITUT PASTEUR on 11 September 1984, clones  $\lambda$ -ARV-2 were deposited by CHIRON CORPORATION on 26 October 1984,

- \* reproaching the companies of the group CHIRON to have marketed HIV detection kits under the name PROCLEIX since September 1999, constituting, according to it, the means of implementation of claims 8 and 11 of its patent, duly authorized by an order of the Presiding Judge, INSTITUT PASTEUR performed a saisie-contrefaçon on 12 July 2005,
- \* these were the circumstances under which INSTITUT PASTEUR served a summons for infringement upon CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED before the *Tribunal de Grande Instance* of Paris;

#### On the patent:

Considering that European patent No. 0 178 978, filed on 17 September 1985 by INSTITUT PASTEUR, under British priority of 19 September 1984, granted on 6 February 1991, was the subject-matter of an opposition procedure before the European Patent Office (EPO) by CHIRON CORPORATION and was maintained with amended claims by way of a decision of the Board of Appeal on 18 November 1999;

The invention, entitled Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV), relates to cloned DNA sequences hybridizable to genomic RNA and DNA of lymphadenopathy-associated virus (LAV), to a process for the preparation of said sequences and to their uses, more particularly to stable probes containing related viruses or DNA proviruses in any medium, in particular in biological samples containing any of them;

The patentee recalls that viruses analogous to LAV have been isolated from patients with AIDS or pre-AIDS, that these viruses, called HTLV-III and ARV Cloned DNA sequences, hybridizable with genomic RNA of lymphadenopathy-associated virus (LAV) and ARV, show many characteristics similar to those of LAV and represent independent isolates of the LAV prototype and that for ease of language, they will all be referred to as LAV;

It sets out that the detection methods available today are based on the recognition of viral proteins, that such a method is described in the patent application EP-A-0 138 667, entitled antigens, means and method for the diagnosis of lymphadenopathy and acquired immune depression syndrome, filed on 14 September 1984, under the priority of patent application No. 8324800 filed on 15 September 1983, that this European patent application describes different recombinant clones of HTLV-III;

It argues that the invention aims at providing new means which should not only be useful for the detection of LAV or related viruses, but also have more versatility, particularly in detecting specific parts of the genomic DNA of said viruses, whose expression products are not always detectable by immunological methods;

The patent comprises 11 claims thus worded:

Claim 1: A cloned DNA which contains a DNA corresponding to the LAV retroviral genome contained in  $\lambda$ -J19 (CNCM I-338), said cloned DNA including LTR elements U3, R, and U5 of said retroviral genome,

Claim 2: The DNA of claim 1 which is a cDNA,

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A

DECISION OF 4 MARCH 2009 Docket No.: 2007/8437 – 5<sup>th</sup> page Claim 3: A cloned DNA which contains a DNA which consists:

- either of a 3' terminal fragment of the DNA contained in  $\lambda$ -J19 (CNCM I-338) corresponding to the LAV retroviral genome, and which has up to 2.5 kb which contains the following restriction sites in the respective orders which follow (from the 3' end to the 5' end):
- 1) either Hind III, Sac I, Bgl II,
- 2) or Hind III, Sac I, Bgl II, Bgl II, Kpn I,
- 3) or Hind III, Sac I, Bgl II, Kpn I, Xho I, Bam HI, Hind III, Bgl II,
- Claim 4: A cloned DNA fragment whose sequence corresponds to the part of the DNA of  $\lambda$ -J19, which extends from approximately Kpn I (6100) to approximately Bam HI (8150) thereof,
- Claim 5: A cloned DNA fragment whose sequence corresponds to the part of the DNA of  $\lambda$ -J19, which extends from approximately Kpn I (3500) to approximately Bgl II (6500) thereof,
- Claim 6: A cloned DNA fragment whose sequence corresponds to the part of the DNA of  $\lambda$ -J19, which extends from approximately Pst I (800) to approximately Kpn I (3500) thereof,
- Claim 7: A probe for the in vitro detection of LAV which consists of a DNA according to any of claims 1 to 6,
- Claim 8: A method for the in vitro detection of viral infection due to the LAV viruses which comprises contacting a biological sample originating from a person to be diagnosed for LAV infection and containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions and detecting the hybridized probe,
- Claim 9: A vector, particularly a plasmid, for the transformation of procaryotic or eucaryotic cells which contains an insert consisting of the DNA of any of claims 1 to 6,
- Claim 10: A microorganism, eucaryotic or procaryotic cell which is transformed by a vector according to claim 9,
- Claim 11: The purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in  $\lambda$ -J19 (CNCM I-338);

Considering that INSTITUT PASTEUR asserts claims 8 and 11 of this document;

#### On the scope of patent claims 8 and 11:

Considering that INSTITUT PASTEUR contends that the accused PROCLEIX assay provides, pursuant to Article L. 613-4 of the French Intellectual Property Code, all the means of implementation permitting the isolation of the RNA covered by claim 11, before providing those of the method permitting the *in vitro* detection of a viral infection due to the LAV virus or HIV-1, which are covered by claim 8 of said patent;

Therefore, setting out that the characterization and the possibility to use the RNA genome of the virus causing AIDS is a prerequisite necessary to the implementation of the diagnosis method

Cour d'Appel of Paris 4th Chamber, Section A

DECISION OF 4 MARCH 2009 Docket No.: 2007/8437 – 6<sup>th</sup> page covered by patent claim 8, INSTITUT PASTEUR first asserts claim 11 which protects the purified RNA of the virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in  $\lambda$ -J19 (CNCM I-338);

The parties are opposed with regard to the scope of patent claims 8 and 11;

In patent law, pursuant to Article 69 of the Munich Convention, the extent of the protection conferred by a European patent or a European patent application shall be determined by the terms of the claims. Nevertheless, the description and drawings shall be used to interpret the claims;

INSTITUT PASTEUR contends that patent No. 0 178 978 constitutes a premier innovation making this patent a pioneering one, so that, according to it, claims 8 and 11 have a scope going beyond their literal meaning;

However, if in the presence of a pioneer invention, the patent may describe one embodiment of the invention and claim any other possible embodiment, on the other hand, even a pioneer patent cannot be granted a general scope if its claims are drafted using restrictive words,

A non-ambiguous claim with a narrow scope cannot be granted a general scope on the pretext of an interpretation when, in particular, the patentee was forced to limit the scope of the claim during the grant and opposition procedures in order to be distinguished from the prior art;

However, in the present case, it is established that the patent application was initially filed with 24 claims and that, following the opposition procedure initiated by CHIRON CORPORATION which gave rise to a ruling in first instance on 9 August, 1994 and to a decision in appeal of the EPO Board of Appeal on 18 November 1994, the granted patent comprises 11 claims of a limited scope;

#### On claim 11:

Considering that claim 11 as filed related to the purified RNAs of LAV viruses which have sizes from 9.1 to 9.2 kb; once amended, it protects the purified RNA of LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in  $\lambda$ -J19 (CNCM I-338);

INSTITUT PASTEUR, stating that none of the prior art documents justifies a strict reading of this claim, nevertheless alleges that it protects, independently of the clone  $\lambda$ -J19, the specific nature of the claimed sequence, the whole purified RNA genome of the LAV virus or HIV-1, an essential compound to the implementation of the protocol for detecting the virus in a biological sample to be tested;

However, the patentee, which amended its claims to confer them a restricted scope, cannot, without damaging the security of third parties, allege that the amendments were not necessary, that the restricted claims would have the same scope as the initial broader claims and that the prior art documents having motivated the amendments would not be relevant;

INSTITUT PASTEUR contends that the complementary DNA (cDNA), to which claim 11 refers, corresponds to the reflection of the RNA genome of the LAV virus (or HIV-1) and cannot be mistaken for the proviral DNA described in the European patent application No. 0 173 529<sup>2</sup> filed on 22 August 1984 by the NIH;

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A **DECISION OF 4 MARCH 2009** Docket No.: 2007/8437 – 7<sup>th</sup> page

<sup>&</sup>lt;sup>2</sup> Translator's note: US patent application in the French text

Although it is not disputed that the clones described in these documents were produced in different ways, it remains that in both cases, the clone which was produced and described is composed of the double-strand DNA corresponding to the viral genome of the HIV;

Under these circumstances, the NIH patent, which discloses the restriction sites of the HIV DNA partly anticipates INSTITUT PASTEUR's patent, regardless of the suggestion of the presence of a pX gene, which does not belong to the HIV genome;

Furthermore, on 31 August 1984, the researchers of Professor GALLO's team published the result of their research in the magazine SCIENCE;

This article called "the ARYA, GALLO article" discloses a general method permitting to purify the HIV RNA from an AIDS patient's blood and teaches that the isolated RNA strands, which have a size of approximately 9 kb, comprise the whole R region at each polyA tail<sup>3</sup>;

It results from the foregoing that the only feature distinguishing claim 11 at issue is the specific nature of the claimed strand, namely its size from approximately 9.1 to 9.2 kb and its ability to hybridize with the cDNA contained in the clone  $\lambda$ -J19;

#### On claim 8:

Considering that INSTITUT PASTEUR contends that patent claim 8 relates to a method for the in vitro detection of viral infection due to the LAV virus which comprises contacting a biological sample originating from a patient suspected of being infected with the LAV (HIV-1), said sample containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions and detecting the hybridized probe;

It alleges that the method covered by this claim protects a novel general means for the detection of the viral charge of AIDS characterized by the hybridization of DNA probes with the viral RNA and that it cannot be limited by the choice of the probe according to claim 7;

Recalling the terms of claim 8 thus worded: a method for the in vitro detection of viral infection due to the LAV viruses which comprises contacting a biological sample originating from a person to be diagnosed for LAV infection and containing RNA in a form suitable for hybridization with the probe of claim 7 under hybridizing conditions and detecting the hybridized probe, it should be noticed that the method comprises two steps: on the one hand, contacting under hybridizing conditions a biological sample originating from a person infected by LAV and containing RNA in a form suitable for hybridization with the probe of claim 7 and on the other hand, the detection of the hybridized probe;

It should be noted that the amendments, which were made by INSTITUT PASTEUR during the examination procedure, led to the limitation of the scope of claim 8 in that it requires using the probe, the subject-matter of claim 7, which depends on claims 1 to 6 protecting cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in  $\lambda$ -J19;

This construction is confirmed by the description referring to (page 17, lines 27 et seq. page 18, lines 10 et seq.) DNA fragments according to the invention and does not describe the general means of probes;

Cour d'Appel of Paris 4th Chamber, Section A

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<sup>&</sup>lt;sup>3</sup> Translator's note: should read "comprise the whole R region at each end and a polyA tail".

It belonged to INSTITUT PASTEUR, during the examination and opposition procedures, to amend the process claim or the probe claims in order to dissociate them from the fragment claims;

INSTITUT PASTEUR cannot contend that claim 8 would cover any diagnostic method, whichever the probe used, on the ground that this claim would indirectly refer to claim 1, which, because of the use of the word "corresponding", would continue to cover any DNA fragment;

Indeed, the Board of Appeal of the EPO, with regard to claim 1, recalled that the word "corresponding" appears to be in the narrow sense of base to base correspondence, subject to the allowable variations which would not substantially alter their capability of also hybridizing with the LAV retroviral genomes, as understood by a person skilled in the art;

Thus, without distorting this decision, it cannot be alleged that the protection of the allowable variations would also extend to the protection of all equivalent DNA fragments;

It follows, recalling if necessary that the article published by the researchers of the NIH, ARYA and GALLO, before the priority date of the patent, already taught the detection of an infection due to the HIV by using labelled probes, that claim 1 covering the cloned DNA contained in  $\lambda$ -J19 and any identical cloned DNA does not protect in any way any DNA fragment, so that claim 8 cannot relate to any diagnostic method regardless of the type of probe used;

Therefore, the scope of claim 8 is limited to a detection method involving the use of probes composed of cloned fragments and including a DNA fragment corresponding to the retroviral genome contained in  $\lambda$ -J19;

The scope of claims 8 and 11 of the asserted patent being thus defined, there is no reason to examine the alternative request for invalidity of these claims lodged by CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED which do not dispute their validity as modified after opposition and as construed;

#### On the infringement of claims 8 and 11:

Considering that INSTITUT PASTEUR, which reproaches to CHIRON for committing acts of infringement, sets out that the accused PROCLEIX assay comprising three steps (a step of isolation of the viral RNA, a step of amplification of the viral RNA and a step of detection of the products resulting from this amplification), provides the means of implementation of claims 8 and 11 of the asserted patent by equivalence;

Considering from a legal point of view that, pursuant to the provisions of Article L. 613-4 of the French Intellectual Property Code, shall be prohibited, save consent by the owner of the patent, to supply or offer to supply, on French territory, to a person other than a person entitled to exploit the patented invention, the means of implementing, on that territory, the invention with respect to an essential element thereof where the third party knows, or it is obvious from the circumstances, that such means are suitable for putting and are intended to put the invention into effect;

INSTITUT PASTEUR does not deny CHIRON's explanations with regard to the implementation method of this kit, namely:

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A DECISION OF 4 MARCH 2009 Docket No.: 2007/8437 – 9<sup>th</sup> page

- capturing target RNAs, which consists in releasing the viral RNAs by cell lysis and capturing the latter by means of capture oligonucleotides which hybridize with target RNAs and are attached to magnetic micro particles.
- a washing step to remove plasma components and nucleic acids other than those fixed to the capture oligonucleotides, it being pointed out that these capture oligonucleotides are synthetic sequences composed partly of DNA and RNA,
- an amplification step implementing the amplification primers, using two primers composed of synthetic oligonucleotides whose function is to initiate the reverse transcription and polymerase steps, the promoter primer including a zone called "promoter 7" necessary for the function of RNA polymerase.
- a detection step consisting in hybridizing the amplified RNA with probes labelled with a luminescent substance, two viral probes, one internal control probe, composed of synthetic oligonucleotides, very short (each smaller than 25 nucleotides) and non contiguous, positioned in several places of the genome,
- an incubation phase during which the probes hybridize with the antisense amplified RNA,
- the captured viral RNA is the whole viral genome, comprising the entire R region at each end, to which the polyA tail is joined, this isolated RNA being described in the aforementioned Arya, Gallo article;

#### On claim 8:

Considering that the accused detection kit uses three types of oligonucleotides hybridizable with genetic material: the capture oligonucleotides, two promoter primers during the amplification step, two labelled probes during the detection step;

INSTITUT PASTEUR alleges that the capture oligonucleotides and the promoter primers constitute means of implementation of claim 8, which covers, according to it, a novel general means consisting in using DNA probes hybridizable with the genomic RNA for the detection of the viral infection by hybridizing viral RNA with DNA;

It adds that these oligonucleotides and these primers are means equivalent to the probes referred to in the asserted claim;

However, it results from the foregoing that the scope of claim 8 is limited to a detection method involving the use of the probe, the subject-matter of claim 7, which depends on claims 1 to 6 protecting cloned DNA fragments defined by their restriction sites and corresponding to the retroviral genome contained in  $\lambda$ -J19;

It should be noted that INSTITUT PASTEUR does not contend at all that CHIRON's detection kit uses the probes of claim 7, composed of fragments of claims 1 to 6;

INSTITUT PASTEUR neither shows the implementation of the other characteristics of claim 8;

Indeed, the capture oligonucleotides and the primers of CHIRON's detection kits are synthetic, so that they cannot fall within the scope of the patent teaching cloned DNA fragments;

These oligonucleotides are not DNA probes but chimerical oligonucleotides composed of

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A

**DECISION OF 4 MARCH 2009**Docket No.: 2007/8437 – 10<sup>th</sup> page

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DNA for one part and of RNA for the second part, the part hybridizing with the HIV RNA being composed of RNA; which can be produced only by chemical synthesis and not by cloning;

Nor do the promoter primers constitute probes of claim 8 since they include a promoter "T7" area necessary to the function of RNA polymerase which is not found in the retroviral genome contained in  $\lambda$ -J19;

INSTITUT PASTEUR cannot use the doctrine of equivalents, since claim 8 does not cover the general means of hybridization but the specific means of hybridization of viral RNA with a probe composed of a DNA fragment which corresponds to the genome contained in the clone  $\lambda$ -J19;

Therefore, the appealed judgment, dismissing the charge for infringement of claim 8, will be affirmed,

#### On claim 11:

Considering that INSTITUT PASTEUR contends that CHIRON's diagnostic assay infringes claim 11 by the supply of means since, according to it, the use of this assay results in the isolation of the RNA of HIV-1;

The supply of means constitutes an act of infringement only if the supplied means relate to an essential element of the invention, namely, taking part in the result of the latter;

In the present case, it should be noted that patent claim 11, as amended, relates to the purified RNA of the LAV virus which has a size from 9.1 to 9.2 kb and which corresponds to the complementary DNA contained in  $\lambda$ -J19;

On the one hand, this claim does not cover a method but a product; on the other hand, it does not characterize the RNA in that it contains all the genetic information necessary to reconstitute the whole genome but in that it defines the RNA which corresponds to the cDNA of  $\lambda$ -J19;

It is not proven at all that implementing this kit would permit the isolation of the specific RNA fragment corresponding to the complementary DNA contained in  $\lambda$ -J19;

It is not denied that the RNA isolated by CHIRON's kits has a size superior to 9.2 kb and contains a complete R sequence at each of its ends, so that it does not fall within the scope of claim 11;

Therefore, the appealed judgment, dismissing INSTITUT PASTEUR's requests for infringement, is worth to be affirmed;

#### On the other requests:

Considering that initiating a court action, like exercising the right to appeal, turns into an abuse giving rise to a claim for damages only in the case of malice, bad faith, gross mistake equipollent to deceit or blameful lack of heed; these requirements are not met in the present case; the counterclaim lodged by CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED will be dismissed:

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A **DECISION OF 4 MARCH 2009** Docket No.: 2007/8437 – 11<sup>th</sup> page

It emerges from the outcome of the decision that INSTITUT PASTEUR cannot benefit from the provisions of Article 700 of the French Code of Civil Procedure; on the other hand, equity demands that it be ordered, on the same ground, to pay CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED the additional sum of 130,000 euros;

#### ON THESE GROUNDS

The Cour d'Appel

Affirms all the orders of the appealed judgment,

And adding thereto

Orders INSTITUT PASTEUR to pay CHIRON HEALTHCARE SAS and CHIRON HEALTHCARE IRELAND LIMITED the additional sum of 130,000 euros for the unrecoverable costs of the appeal proceedings,

Dismisses all the other requests,

Orders INSTITUT PASTEUR to pay the costs and holds that these costs can be collected pursuant to the provisions of Article 699 of the French Code of Civil Procedure.

THE CLERK

THE PRESIDING JUDGE

Cour d'Appel of Paris 4<sup>th</sup> Chamber, Section A **DECISION OF 4 MARCH 2009** Docket No.: 2007/8437 – 12<sup>th</sup> page

#### AFFIDAVIT OF MR. GASPARD MONTRETOU

I am Gaspard Montretou, French citizen born on 1<sup>st</sup> of April 1975 in Marseille, residing 25 place du Sud, 13470 Soleil-sur-Pastis.

I graduated from the Civil Engineering Industry Master of Marseille in 1997. I then obtained a PhD in 2002 in Spain, at the University of Barcelona, on "roofs: how to benefit from the climatological elements". Since 2003, I am assistant Professor at Université des Sciences of Marseille, then full Professor in 2005. I lead a pioneer research team on solar energy. I have been recognized by the profession on numerous aspects of this solar energy research: I was a lauréat du concours de l'innovation de l'état (winner of the country innovation competition) in 2010 and a pyramide d'or (golden pyramid) at the "pyramides de l'Innovation Universitaire 2012" (Pyramids of the University Innovation). I am a consultant for La Nuova Tessera since 2013, and the inventor of the patent filed in 2017 by La Nuova Tessera and Université des Sciences of Marseille (EP 2 305 607). With this patent, I have won the "inventor of the year" price by the European Patent Office in 2021. This price recognizes initiatives that use technology to solve a problem within the United Nations Sustainable Development Goals framework.

I have been asked by La Nuova Tessera and Université des Sciences of Marseille's team and lawyers to provide comments on my participation to the Batomat 2017 fair, which took place in Lyon on October 14, 2017. Specifically, they requested a complete, open and factual presentation of what I shown, and on the explanations or comments I discussed with members of the public (potential customers).

This fair was a success: La Nuova Tessera obtained contact details of 567 potential customers. I probably discussed with half of them in a crowd discussion, and with around 100 individuals in more in-depth discussions. My recollection of this fair is quite vivid given that I was deeply involved in its organization but it was very crowded and I have absolutely no recollection whatsoever of Ms. Louise Martin.

I had prepared my speech in advance, and gave approximately the same information to each of these potential clients. I then answered the questions they had, but mostly directed them to the maquette of a building with a roof tile according to the invention. This maquette was protected by a glass dome that the crowd or potential clients could see from about 1 meter but could not touch. Some prototypes of roof tiles according to the invention were also displayed under similar dome glasses, mounted as in a roof, therefore protected by rafters on their sides.

La Nuova Tessera lawyers had explained me, prior to the fair, that if something is publicly shown, disclosed or described before a patent is filed, then it cannot be patented any more. They also explained me that Bad Glass uses this 2017 Batomat fair to argue that the patent EP 2 305 607 is invalid.

Although as mentioned above I was present at this fair with some samples and maquettes, and although the patent was not yet ready at that time, I am sure the invention was not disclosed. Indeed, the potential clients could not see all the components of the invention, but only some parts of it. Specifically, nobody could see (i) that the plate below the glass was made in metal (ii) that there are some fluidetight passageway below this plate (iii) and even less how the heat can be transferred from the metal plate to the fluid. I discussed a lot of things with a lot of people, but I do not recall having discussed the plate or its composition, or the fluidetight passageway. I think I would remember if I had discussions or questions on these specific aspects of the tile. Questions were more about transparency

of the glass, longevity of the tiles, weight of the tiles, or time increase on the construction site to put these tiles on a roof.

In her affidavit, Ms. Louise Martin writes that I would have mentioned the existence of the metal plate to her. As I said above, I have no recollection of having spoken to Ms. Louise Martin, since I spoke to a lot of person this day, but I am quite positive that I have not mentioned that the plate was of metal. However, how she correctly mentions, the plate was slightly visible under the dome, since it is shorter than the photovoltaic module, but one cannot infer with certainty from the mere appearance of the plate that it is made of metal (it would have been made of a composite material, for instance).

The dome glasses was never removed during the fair. They were anyway so fragile that nobody from La Nuova Tessera team could have moved them during the exhibition, and the tiles are very heavy.

La Nuova Tessera and Université des Sciences of Marseille's lawyers also showed me a youtube video (presented as exhibit of Bad Glass court submissions dated 15 July 2024), and explained me that from this video, Bad Glass alleges that one could deduce from the video "the main advantage of the new tiles compared to prior art is that the new products allow heat dissipation thanks to the use of an ingenious system using the passing of fluid to cool down the whole system and present the prototype, showing the metal plate with flat fluid-tight passageways below the transparent cover".

This is just not true. This video only shows combination of a roof tile comprising a transparent cover and a solar collector. The video contains no explanation of the internal features of the roof tile. It is only because Bad Glass reverse engineered the patented invention that they learned, a posteriori, the material of the plate (metal). What can be seen on the video, and what could be seen under a dome glass during the exhibition, is an unnamed/uncharacterized material below the transparent cover. No one can affirm it is metal. Also, the transparent covers only shows this unnamed/uncharacterized material (which is indeed metal). This material being very opaque, what is below cannot be seen without disassembling the tiles.

I think Bad Glass looks at the video knowing how the patented tiles are made, and tries to read more things than can really be seen on these tiles. But when you have never touched or disassembled the tile of the invention, you cannot know that the plate is a metal plate, or that there are flat fluid-tight passageways below the metal plate.

I understand this affidavit will be used before a Court, in the context of a patent litigation, and I confirm that what is in the present affidavit is true, to the best of my knowledge.

A copy of my ID card is attached to this affidavit.

Made in Soleil-sur-Pastis

On 31 August 2024

**Gaspard Montretou** 

WS0101.35055444.1

# Schedule 1 - Copy of ID card





**From:** Sorare, Laura

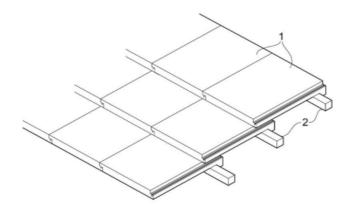
**Sent:** Monday 25 September 2017 11:15 **To:** CLIENT\_ALL Distribution List

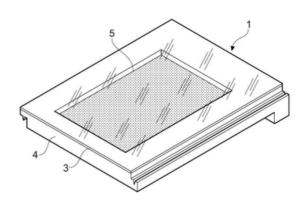
**Cc:** Montretout, Gaspard < g.montretout@inventor.com>

**Subject:** INVITATION: Meet us at Batomat 2017 to discover our new roof tiles!

#### Dear Customers,

We offer you the opportunity to discover our new photovoltaic roof tiles that are easy to use and install:





These innovative photovoltaic roof tiles have the advantage by their constitution and the choice of materials to be incredibly efficient to supply electricity (<u>very high transparency</u> of 91,5% of the glass of the cover of the solar collector). They are also able to heat a building or a house thanks to a flat fluid-tight passageway (connectors and tubes filled with <u>circulating</u> fluid located behind the solar collector).

We are proud to introduce you to this new technology at Batomat show on 14 October 2017. Famous Professor G. Montretou from the University of Marseille, France, will be happy to show you two different versions of this revolutionary photovoltaic roof tile in detail and explain its structure.

In case you cannot attend our presentation at Batomat, you can find our promotional video at the following URL: <a href="https://www.youtube.com/LNTaB2017">www.youtube.com/LNTaB2017</a>, where you will find the explanation of the functioning of the new photovoltaic roof tile.

We are looking forward to meet you at Batomat. Our commercial team remains available to answer any questions you may have.

Your sincerely,

La Nuova Tessera team





# Video from La Nuova Tessera

https://we.tl/t-AaNX2fAxSL



Olivier LAROCHE

**Bailiff** 

Henri WATSON

15 rue de la Baume, 75008 Paris

Email: laroche@wanadoo.fr

Telephone: 01.75.24.43.67

# BAILIFF REPORT ON THE INTERNET



Université des Sciences de Marseille and La Nuova Tessera

V.

**Bad-Glass** 

Case No. 2024-0099 - Bailiff's deed No. 159443

Case No. 2024-0099 Bailiff's deed No. 159443

# **BAILIFF REPORT ON THE INTERNET**

**DATE:** 13 July 2024

Acting upon request of the company **Bad-Glass**, a brickdury company incorporated under the laws of the State of Tiledavia, Registration No. 2609567, having its head office at 54, Imagination road, 1227 Tiledavia.

#### **STATING THAT:**

Bad-Glass is being sued for infringement of the patent EP 2 305 607 B1 before the Central Division, Paris Seat of the UPC. Bad-Glass alleges that the patent is invalid. It has therefore the greatest interest in establishing a report of the following YouTube page's content on the internet: <a href="https://www.youtube.com/LNTaB2017">www.youtube.com/LNTaB2017</a>.

It then requested me, in order to preserve its rights, to establish all necessary facts and to draw up an official report.

I, OLIVIER LAROCHE, COURT BAILIFF, WHOSE ADDRESS IS 15 RUE DE LA BAUME 75008 PARIS, CERTIFIES THAT I REPORTED THE FOLLOWING:

#### I – TECHNICAL STEPS PRIOR TO A BAILIFF REPORT ON THE INTERNET

#### **AFNOR Standards NF Z67-147**

1) The present report is made on the computer workstation described below:

#### Desktop computer

Model: HP ProDesk 400 G1 MT
Motherboard HP18E9

Processor: Intel® Core™ Duo CPU E8400 @ 3.00GHz, 3000 MHz, 2 logical processor(s)

Physical storage: 4096 MB

Graphics Card: Intel® HD Graphics 4400

Hard disk: TOSHIBA DT01ACA050 SCSI Disk Device (500GB)

DVD-Rom drive: Hewlett-Packard DVDRAM GT80N

Monitor Type: ViewSonic VG390m-3-19 inch

Network Card: Realtek Semiconductor RTL8168/8111

Operating system: Windows 7 Professional Medis Center 6...

DirectK: Version 11.00

Windows Performance Index: 4.8 of 7.9

I am connected to my office's computer server.

The screen copies are made using the "Print Screen" button and are directly incorporated into this report.

2) I synchronise my computer workstation's internal clock with the internet time server "time.windows.com" by updating "Date and Time Properties", "internet time" in my operating system.

The clock was synchronised with time.windows.com on 13 July 2024 at 2.45pm.

- 3) I update my antivirus software Ka Kaspersky Endpoint Security 10 For Windows
  - Then I run a virus scan.
- 4) I update my spyware removal program

Malwarebytes ANTI-MALWARE

Then I run a scan.

- 5) I determine the configuration of my computer workstation (configuration mentioned above) using the software: PC WIZARD 2014 Classic Edition Version 2.13
- 6) I access the WAN via a router connected to the server and whose model is D-LINK ADSL ROUTER model No. DSL6502T

Via network map: Realtek Semiconductor RTL8168/8111 Gigabit Ethernet Adapter

7) My provider is WANADOO/ORANGE

Subscription: Internet pro solo - 8M

8) I determine the MAC address of the active network card of my work machine by using the command "ipconfig/all" preceded by cmd+ok in the command prompt of my operating system and note that it is identical to the one obtained using the free BeLarc Advisor software.

I note that DHCP is inactivated.

The address is: 2C:44:F:3A:A5:C1.

- 9) I then perform various purging operations, as follows:
  - I do a full purge and empty my recycle bin completely
  - I make sure that the CD Rom and floppy drives are empty;
  - I make sure there is no external removable storage media on the computer.
  - Complete purging of the browsing history and setting of my browser parameters by going to: "Tools", "Options", "Privacy", "History" "Never keep history".
  - Setting of the local cache and complete purging of the local cache via the path: "Tools",
     "Options", "Advanced", "Network", "Cached web content" button, "Empty now" button
- 10) I make sure that my browser is not set to use a proxy by the path: "Tools", "Advanced", "Network" tab, "Connection", "Settings" I make sure that for the Proxy server configuration to access the Internet "No proxy" and checked as follows:

Connection settings

Configuration of the proxy server to access the Internet

- No proxy
- 11) I configure my browser to accept cookies
- 12) I set a blank page as my start page via the path: "Tools", "Options", "General" tab, "Startup", When Firefox starts "Show a blank page".

13) I get my "WAN" IP address - by using the command "ipconfig/all" in my operating system's command prompt and connecting to the page

http://www.mon-ip.fr

83.1557.21.85

14) I do a final clean-up using CCleaner.com

# II - REPORT

After having done all the necessary technical measures to ensure that the report is valid.

At 3.15pm, I start my findings.



I start my web browser.

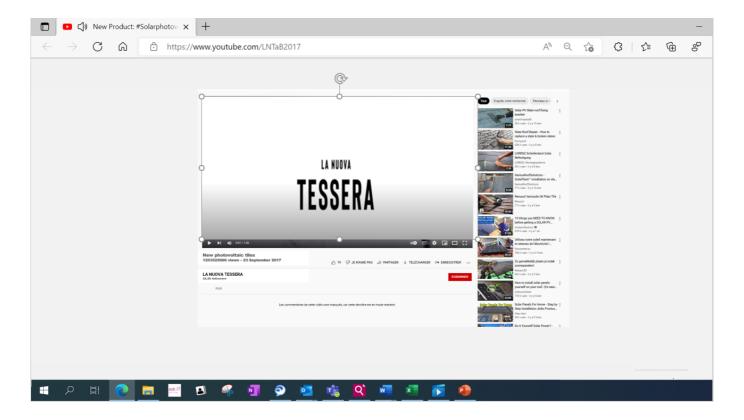
I am not connected to a proxy.

I enter the following URL address in the browser's address field:

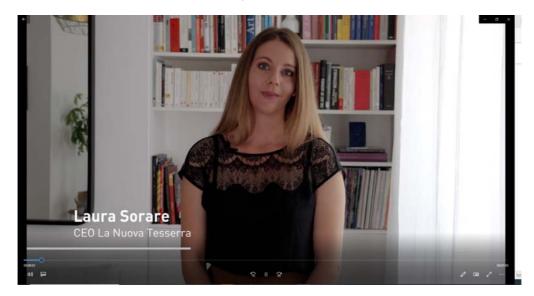
www.youtube.com/LNTaB2017

And press "Enter".

A Youtube video appears:



Underneath the Youtube video, I can read within the description section of the video that the woman in the video is the CEO of La Nuova Tessera, and I make screenshots:









I downloaded the video, which is enclosed to the present report.

# THESE ARE MY FINDINGS.

I certify that I have done and wrote this bailiff report.

Made for all legal intents and purposes.



Encl: video in mp3 format



#### Affidavit of Ms. Louise Martin

#### Introduction

- 1. I, undersigned, Ms. Louise Martin, was born on 6 December 1965, in Paris, and I am residing at 8 rue de la Boétie, 78008 Paris.
- 2. I was contacted by Pauline Debré, François Rivière et Oliver Tischner, representatives of Bad-Glass, to describe my visit of the Batomat Fair 2017 in Lyon. I have never met them before and if I had heard the company name "Bad-Glass" before, I never worked for Bad-Glass, nor had or have any kind of relationship with it.
- 3. Bad-Glass representatives explained the context of the present proceedings, and notably told me that Bad-Glass had been sued by the Université des Sciences de Marseille and the start-up La Nuova Tessera, in France and before the UPC, alleging infringement of their patent EP 2 305 607 B1. I have no past or present relationship with the claimants either: I discovered La Nuova Tessera's existence and products during the Batomat Fair 2017 and I did my studies in Bordeaux and not in Marseille.
- 4. I see no actual or potential conflict of interest that may affect my impartiality in signing this affidavit.

#### **Affidavit**

- 5. On 14 October 2017, I visited the Batomat Fair in Lyon. I am an engineer and architect and I therefore try to attend the Batomat Fair, which is the world's leading construction exhibition, every year. It is indeed a very good event to discover new technologies that I can use in my job, and to discuss with professionals of the sector.
- 6. At the time of the fair, I was working on a big project for a client very sensitive to environment issues and willing to build a green house. Therefore, I paid specific attention to all booths presenting new environment technologies and stopped notably at La Nuova Tessera's booth.
- 7. I was first intrigued by the maquette of a building with the prototype roof tiles, protected by a glass dome, which was located behind the booth. I could not approach it closer than one meter. However, since I have good eyesight, I could clearly see the tile prototypes.
- 8. In front of the booth, there was a man who came to me and introduced himself as the inventor of the tiles presented. He gave me his business card so I learned his name: Gaspard Montretou, which is a name you don't forget if you are a French speaker!
- 9. I told him I was curious about the product and asked him how it worked. He explained that this new product was revolutionary in that it allows an improved heat dissipation compared to existing tiles. I did not remember all details, but I remember that this was because of the way fluids could go through the module and cool down the metal plate, itself used to cool down the photovoltaic module. He also explained that another advantage of the structure was that the heat dissipated could also be used to heat the water you used as fluid.
- 10. I thought that this was very interesting and decided to look deeper into that product. I had taken some pictures of the maquette and once back home I zoomed to look at the details. I could actually see on those pictures the metal plate the inventor had mentioned because of the transparency of the cover, and the fact that the photovoltaic module was shorter than the metal plate below it.
- 11. I had suggested to my client to use the Nuova Tessera's tiles on its new home but considering that these were really expensive (and even more expensive that other competitor's products), he decided against.

12. I am aware that this affidavit will be produced in Court and that a false declaration may lead to criminal sanctions.

Made in Paris on 18 July 2024,



Enclosed: my national ID





#### Affidavit of Ms. Louise Martin (updated)

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Made in Paris on 18 July 2024,

Enclosed: my national ID

Enclosed: pictures I took at Batomat fair in 2017

Lowise Hankin

Schedule 1: Ms Louise Martin ID



Schedule 2: Pictures taken by Ms Louise Martin









# **CLIENT ALERT**

Unified Patent Court: The Competent Court — Part II

# Pièce n° Vo

#### March 29, 2016

In our <u>previous alert</u>, we explained for what matters the UPC will be granted exclusive competence, and how parties can best avoid this exclusivity: (i) during a transitional period of seven or up to fourteen years from entry into force of the UPC Agreement, several specific claims can still be brought either before the UPC or before the national court (Article 83(1) UPC Agreement); (ii) patentees also have the possibility to completely opt-out from the exclusive competence of the UPC (Article 83(3) UPC Agreement).

In the second part of this UPC alert, we will describe more fully the legal framework in order to determine the exact national court or the exact division of the UPC that will be competent to rule on a specific issue.

#### 1. How to determine whether the UPC or the national courts have competence?

As <u>explained in our first alert</u>, there are various circumstances in which the parties can choose to bring their claim either before the UPC or before a national court. This is the case during the transitional period, but also thereafter in cases where the UPC has a non-exclusive competence. European Regulation 1215/2012 on jurisdiction and the recognition and enforcement of judgments in civil and commercial matters (the so-called Brussels I Regulation (recast), hereafter the Regulation) will apply to determine the competent court in international matters (Article 31 UPC Agreement). The Brussels Regulation has even been amended specifically in the light of the UPC (Regulation 542/2014 amending Regulation 1215/2012 as regards the rules to be applied with respect to the Unified Patent Court and the Benelux Court of Justice, or hereafter the amended Regulation).

• When the defendant is domiciled in one of the participating member states

In accordance with the new Article 71 of the amended Regulation, the UPC will have jurisdiction over claims regarding the unitary patent when the defendant is domiciled in a participating member state. In the cases of shared or parallel competence of the UPC and the national courts (*cf.*, supra), the competent court will be determined on the basis of the general rules of the new Regulation 542/2014 (Article 31 UPC Agreement).

Particularly significant is the proposed amendment which explicitly states that the UPC will be considered a "court" within the meaning of the Regulation, competent to settle disputes relating to classic European patents that have not been opted out and European patents with unitary effect (Article 71a of the amended Regulation). This will have interesting consequences. For instance, since the UPC as a whole is deemed a "court" in the sense of the Regulation, Article 4 of the Regulation can come into play: this Article grants jurisdiction to the court of the defendant. However, this is not a guarantee that a defendant will always play a UPC 'home game'. Due to the internal division of competences among the different divisions of the UPC, a defendant could end up before a division of the UPC court that is located in another participating member state of the UPC.

#### Example:

As Sweden is one of the UPC participating member states, a Swedish defendant could be sued before the UPC.



However, Sweden does not have its own UPC local division. Another division of the UPC will therefore have jurisdiction, such as for example the Central Division (in Paris, London or Munich) or the Baltic-Nordic regional division.

Courts of a non-UPC state could even be competent to hear a dispute relating to a unitary patent right.

#### Example:

If a Spanish patent holder of a unitary patent suffers damage in Spain, it could choose to initiate an infringement action before the Spanish national court (note: Spain is not a participating member state) against a French defendant allegedly infringing its unitary patent in France (Article 7.2 Regulation). (For example, this may happen if the Spanish assets or profits of the unitary patent holder are damaged by the alleged patent infringement in France.) In that case, it would be possible for the Spanish national court to establish its jurisdiction on the basis of Article 7.2 Regulation and pronounce judgment regarding unitary patent rights that concern territories beyond its forum.

When the defendant is not domiciled in one of the participating member states

The Regulation being applicable, also means that defendants domiciled in non-participating member states could be sued before the UPC on the basis of other jurisdictional rules, such as "the place where the harmful event occurred or may occur" (Article 7.2 Regulation).

The new Article 71ter (2) of the amended Regulation furthermore provides that Chapter II of the Regulation will replace the national private international rules in case the defendant is not domiciled in a participating member state and the competence of the UPC is not otherwise established.

#### Example:

A Chinese defendant can be brought before the UPC for infringement of a European patent (whether with or without unitary effect) if that infringement has occurred in one of the participating member states having ratified the UPC agreement.

Moreover, the amended Regulation provides for an entirely new "long-arm jurisdiction" for the UPC which would even be competent to rule on damages suffered outside the Union resulting from the infringement of a European patent. Such jurisdiction will only be established if property belonging to the defendant is located in one of the UPC participating member states and if the dispute has sufficient connection with any such member state.

Choice of forum by the parties?

Pursuant to the general rule of Article 25 Regulation, parties can always include a choice of court clause in their licensing contract. This competence will be exclusive and does not relate to the domicile of the parties.

As the UPC has very limited competence to pronounce judgment on contractual issues (with the exception of contractual issues constituting a "related defense" against an infringement claim), the practical relevance of this choice of forum will be rather limited.



#### 2. Which court will have jurisdiction when the same parties have brought the same issue before different courts?

The application of the general *lis pendens* principle, stipulated in Articles 29-32 Regulation provides that, where proceedings involving the same cause of action and between the same parties are brought in the courts of more than one member state, any court other than the court first seized shall of its own motion stay its proceedings until such time as the jurisdiction of the court first seized is established. This principle applies to the shared competence of the UPC and the national courts of participating member states during the transitional period, as well as to the division of competence between the UPC and the national courts of non-participating member states.

However, when the same issue between the same parties is pending between two different divisions of the UPC, the provisions of the UPC Agreement will apply (Article 34 UPC Agreement).

The priority for the court first seized moreover only applies to the extent that both proceedings relate to the patent rights for the same territory. Difficulties could arise when an infringement action is pending before the national court of a participating member state and another infringement action is initiated before the UPC. The national court can only pronounce judgment with respect to the limited territory of that participating member state, whereas the decisions of the UPC cover all territories of all participating member states. Article 34 UPC Agreement does not seem to allow for a territorially limited judgment. Given that the UPC will have to stay its proceedings in the event that a national infringement action is initiated first, it would seem that a national 'torpedo' remains a possibility, at least during the transitional period. However, these *lis pendens* provisions are not applicable to temporary injunction proceedings (Article 35 Regulation). Hence, a request for preliminary measures can always be filed with the UPC, even pending a national infringement action.

#### Example:

When an infringement action is pending before the Spanish national court (note: a non-participating member state), the Spanish court in principle has jurisdiction to rule only on the infringement committed on the Spanish territory. If a second action relating to the same patent and between the same parties is thereafter initiated before the UPC, the *lis pendens* principle will not require the UPC to stay its proceedings.

Moreover, in case of the "long-arm jurisdiction" of the UPC, the UPC might also have to stay its proceedings if a court of a non-participating member state is seized with proceedings between the same parties concerning the same cause of action.

#### Example:

If in the previous example, damage were suffered in Spain, the UPC would also be competent to rule upon that damage if the defendant owns property in one of the participating member states and the dispute moreover has a sufficient connection with one of the UPC participating member states.

However, given that the infringement action with related damages claim is pending before the Spanish national court, the UPC will have to stay its infringement proceedings of its own motion. Another possibility is of course that the UPC declares itself not competent to rule on the damages incurred in Spain. In that case, the UPC will be able to pronounce judgment on all remaining issues.

#### 3. Before which division of the UPC can a claimant bring its claim?



Article 33 UPC Agreement contains detailed jurisdictional rules regarding the competence of the various divisions of the Court of First Instance of the UPC. The principle: It explicitly allows the parties to agree to bring their action before the division of their choice, including the central division (Article 33(7) UPC Agreement). However, if no agreement is made, which will be the most likely scenario, the rules of Article 33 UPC Agreement apply.

The following cases will be brought before the local division hosted by the participating member state **where the actual or threatened infringement has occurred** or may occur, or the appropriate regional division for that participating member state:

- Infringement actions with respect to patents and SPCs and related defenses.
- Actions for provisional and protective measures and injunctions.
- Actions against defendants having their residence, or principal place of business or, in the absence of residence or principal place of business, their place of business, outside the territory of a participating member state.

The following cases will be brought before the local division hosted by the participating member state where the defendant or, in the case of multiple defendants, one of the **defendants has its residence**, or principal place of business, or in the absence of residence or principal place of business, its place of business, or the appropriate regional division for that participating member state:

- Infringement actions with respect to patents and SPCs and related defenses.
- Actions for provisional and protective measures and injunctions.
- Actions for damages or compensation for licenses of right (published patent applications, prior use, etc.).

The **central division** will be competent for the following cases:

- Actions for declaration of non-infringement of patents and SPCs.
- Actions for revocation of patents and invalidity of SPCs.
- Actions concerning decisions of the European Patent Office in carrying out the administrative tasks referred to in Article 9 of Regulation (EU) No 1257/201.
- Actions against defendants having their residence, or principal place of business or, in the absence of residence or principal place of business, their place of business, outside the territory of a participating member state.
- If the participating member state concerned does not host a local division and has no appropriate regional division.
- If an action referred to in Article 32(1)(a) is pending before a regional division and the infringement has occurred in the territories of three or more regional divisions, the regional division concerned shall, at the request of the defendant, refer the case to the central division.
- Counterclaims for revocation of patents and for declaration of invalidity of SPCs, when the local or regional division, competent to hear the infringement claim, decided to refer the counterclaim or the entire case (with the agreement of the parties) to the central division.

# 4. Can the defendant bring another claim before a different division?

No. Pursuant to Article 33(2) UPC Agreement, any action between the same parties on the same patent may not be brought before any other division.



If the same action between the same parties and relating to the same patent is brought before different divisions, the division first seized will be competent for the entire case. The divisions seized later must declare the action inadmissible.

The defendant can nevertheless request that the case be referred to the central division if the infringement has occurred in the territories of three or more regional divisions.

Moreover, if the defendant wants to bring a <u>counterclaim for revocation</u>, it is up to the local or regional division to choose whether or not to bifurcate the proceedings. In accordance with Article 33(3) UPC Agreement, the local or regional division concerned has the discretion (i) to proceed with both the infringement action and the counterclaim for revocation, or (ii) to refer the counterclaim to the central division and, accordingly, to suspend or proceed with the action for infringement, or (iii) provided both parties agree, to refer the entire case for decision to the central division.

#### 5. Which court is competent when multiple defendants are involved in the proceedings?

An infringement action can only be brought against <u>multiple defendants</u> when all of the defendants have a commercial relationship and in case the action relates to the same alleged infringement (Article 33 (1)(b) UPC Agreement). No further explanation has yet been provided on the interpretation of "commercial relationship".

When actions relating to the same patent (whether or not between the same parties or involving defendants without a commercial relationship) are pending before different divisions of the UPC, the divisions concerned may decide that it is in the interest of the proper administration of justice and necessary in order to avoid inconsistent decisions to join these cases (Rule 340 Rules of Procedure). This decision can however only be pronounced after hearing the parties and if the proceedings are sufficiently connected.

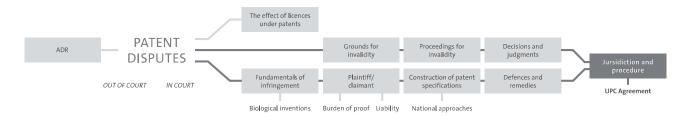
For more information, please contact the professional(s) listed below, or your regular Crowell & Moring contact.

#### Jan-Diederik Lindemans

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# **Unified Patent Court Agreement (UPCA)** (Supplementary reading)



# **General and institutional provisions**

The Unified Patent Court (UPC), a specialised patent court common to the European Union's member states, will decide on disputes relating to European patents and unitary patents (European patents with unitary effect). The Court is based on an international agreement – the Agreement on a Unified Patent Court of 19 February 2013 (UPCA) – which was signed by 25 member states of the European Union, and will enter into force once ratified by at least 13 member states, including the three states in which the highest number of European patents had effect in 2012.

With respect to the traditional European patent, the Court will be able to decide in one decision for all those countries where the EP is registered, unless the patent has been "opted out" of the system by the patentee. With respect to the unitary patent, the Court has exclusive jurisdiction for all 25 participating member states.

#### **General provisions**

#### **Unified Patent Court**

Currently, the national courts and the judicial authorities of the contracting states to the European Patent Convention (EPC) are competent to decide on the infringement and validity of the respective national tiers of a European patent.

The UPCA creates a specialised patent court (Unified Patent Court, or UPC) with exclusive jurisdiction for litigation relating to (classic) European patents and European patents with unitary effect (unitary patents), and which is bound by EU law.

# **Definitions**

Article 2 defines certain terms used in the Agreement. These definitions are self-explanatory.

Article 1 UPCA **Unified Patent Court** 

Article 2 UPCA Definitions

It should be borne in mind that the term "patent", when used in the Agreement, is limited to European patents and unitary patents. It does not cover national patents.

#### Scope of application

The Agreement applies to unitary patents, supplementary protection certificates (SPCs) issued for a product protected by a European or unitary patent, European patents in force at or granted after the entry into force of the Agreement, and European patent applications pending at or filed after the entry into force of the Agreement.

**Article 3 UPCA** Scope of application

#### Legal status

The Court has legal personality in the member states, in accordance with the national law, and is represented by the President of the Court of Appeal.

**Article 4 UPCA** Legal status

#### Liability

The contractual liability of the Court is governed by the law applicable to contractual obligations under the **Rome I Regulation**, where applicable, and otherwise under the lex fori.

The non-contractual liability of the Court for damages caused by the Court or its staff is determined under the laws of the member state where the damage occurred, and the courts of that member state have jurisdiction to settle related disputes.

**Article 5 UPCA** Liability

Regulation (EC) No 593/2008 of the European Parliament and of the Council of 17 June 2008 on the law applicable to contractual obligations (Rome I) (OJEU L 177, 4.7.2008, p. 6) including any subsequent amendments

## **Institutional provisions**

#### The Court

The UPC consists of

- (1) A Court of First Instance, comprising:
  - A central division (based in Paris, with sections in London and Munich, each with specific fields of technology attributed to them see Annex II to the Statute).
  - If a member state so chooses: local divisions (one for each country + one extra per 100 cases, and a maximum of four).
  - If any two or more member states so agree: regional divisions.

The central division is composed of two legal judges and one technical judge, while local and regional divisions consist of three legal judges and optionally one technical judge. All divisions have a multinational composition, as determined under Article 8.

Article 6 UPCA The Court

Article 7 UPCA The Court of First Instance

Article 8 UPCA Composition of the panels of the Court of First Instance

(2) A Court of Appeal with its seat in Luxembourg (with a multinational composition of three legal and two technical judges), and;

Article 9 UPCA
The Court of Appeal

(3) A Registry, set up at the seat of the Court of Appeal and with subregistries at the divisions of the Court of First Instance.

Article 10 UPCA The Registry

The Registry is managed by the Registrar, who assists the Court and the judges in the performance of their functions and is responsible for the organisation and activities of the Registry (Article 23 of the Statute).

Statute of the Unified Patent Court

It is the responsibility of the Registry to keep the register, including records of all cases before the Court, and keep lists of the pool of (i) judges, (ii) patent attorneys entitled to represent parties before the Court, and (iii) experts. It must also keep and publish notifications and withdrawals of opt-outs under the transitional provisions (see Article 83), as well as ensure that opt-out information is notified to the EPO. It must also publish Court decisions and annual reports.

#### The various committees

Articles 11–14 UPCA Committees

To ensure the effective implementation and operation of the Agreement, administrative, budget and advisory committees will be set up, with representatives from each member state. Further details on these committees can be found in **Articles 12, 13 and 14 UPCA** respectively. Specific tasks are described throughout the UPCA and the Statute.

#### **Judges of the Court**

Eligibility criteria for judges and the appointment procedure are described in Articles 15 and 16 respectively.

Article 15 UPCA Eligibility criteria for the appointment of judges

#### Judicial independence and impartiality

Article 16 UPCA
Appointment procedure

The Court, its judges and the Registrar enjoy judicial independence. In the performance of their duties, the judges are not bound by any instructions.

Article 17 UPCA
Judicial independence and impartiality

Besides other judicial functions at national level, full-time judges may not engage in any other occupation, unless an exception is granted by the Administrative Committee. Part-time technically qualified judges may exercise other functions, provided there is no conflict of interest. In the event of a conflict of interest, the judge concerned may not take part in the proceedings.

Further rules on conflicts are set out in the Statute.

#### **Pool of judges**

The legally and technically qualified judges from the Court of First Instance form a pool. They are allocated to the relevant divisions based on their legal/technical expertise, linguistic skills and experience.

Article 18 UPCA **Pool of Judges** 

The technically qualified judges are also available to the Court of Appeal.

# **Training framework**

A judges' training framework with facilities located in Budapest will focus on:

- internships in national patent courts or divisions of the Court of First Instance
- linguistic skills
- technical aspects of patent law
- courses on civil procedure for technically qualified judges
- the preparation of candidate-judges

Article 19 UPCA **Training framework** 

# The Primacy of Union law, liability and responsibility of the Contracting **Member States**

#### Primacy of and respect for Union law

The UPC must apply Union law and respect its primacy.

Article 20 UPCA Primacy of and respect for Union law

#### Requests for preliminary rulings

The UPC must co-operate with the Court of Justice of the European Union (CJEU). In particular, it can file requests with the CJEU to give preliminary rulings on the interpretation of EU treaties and the validity and interpretation of acts of Union institutions, bodies, offices or agencies.

Decisions of the CJEU are binding on the UPC.

Article 21 UPCA Requests for preliminary rulings

#### Sources of law and substantive law

#### Sources of law

The UPC must base its decisions on Union law, the UPC Agreement, the EPC, other applicable international agreements binding on all member states, and national law.

In cases where national law comes into play, including the law of noncontracting states, the applicable law is determined following private law rules. These may be under directly applicable provisions of Union law or,

Article 24 UPCA Sources of law

Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements (OJEU L 361, 31.12.2012, p. 89) including any subsequent amendments

in the absence thereof, under relevant international instruments or, in the absence thereof, under national law provisions.

#### **Substantive law**

The Agreement contains some provisions of substantive patent law. Most of them reflect similar provisions under national law (many of which have a common origin), but some changes are introduced as well. These mainly relate to the territorial effect of European and unitary patents.

Article 25 UPCA deals with direct infringement, giving the patentee the right to prevent unauthorised third parties from:

Article 25 UPCA Right to prevent the direct use of the invention

- (a) making, offering, placing on the market or using a patented product, or importing or storing it for those purposes;
- (b) using a patented process or, where the third party knows or should have known that its use is prohibited without authorisation, offering it for use in any of the designated contracting member states;
- (c) offering, placing on the market, using, or importing or storing for those purposes a product obtained directly by a patented process.

Under Article 26 UPCA, which deals with indirect infringement, the patentee is entitled to prevent unauthorised third parties from supplying or offering to supply, in any of the designated contracting member states, any persons other than those entitled to exploit the invention, with means relating to an essential element of the invention, for putting the invention into effect in the territory of the designated contracting member states, when the third party knows or should have known that those means are suitable and intended for putting that invention into effect.

Article 26 UPCA Right to prevent the indirect use of the invention

This does not apply to staple commercial products, except where the third party induces the receiver to perform a direct infringement.

Article 27 UPCA lists the limits to the effects of a patent, including among others, private or experimental use, breeding plant varieties and a Bolartype exemption. It should be noted that the experimental use exemption under the Agreement is somewhat stricter than in certain European countries, and is limited to "acts done for experimental purposes relating to the subject-matter of the patented invention" (Article 27(b)). Also, the Bolar-type exemption (Article 27(d)) was not transposed in the same way in every EU member state. Consequently, certain companies may find themselves in a different legal position depending on whether they face a national, European or unitary patent, and depending on whether they are before the UPC or a national court.

Article 27 UPCA Limitations of the effects of a patent

Somewhat at odds with the basic principle of a "single territory" for European and unitary patents is the regime for prior user rights. These are left to be decided under national law and remain restricted to the local level of the contracting member state only (Article 28 UPCA). In other words, a prior user right in one country does not give the right to apply the invention in another contracting member state.

Article 28 UPCA Right based on prior use of the invention

On the other hand, the Agreement provides for a Union-wide exhaustion rule in respect of the rights conferred by a European patent, stipulating that the patentee's rights do not extend to acts concerning a product covered by a patent after it has been placed on the market in the EU by him or with his consent, except in cases where there are legitimate grounds for him to do so (Article 29 UPCA).

Article 29 UPCA Exhaustion of the rights conferred by a European patent

#### International jurisdiction and competence

#### Overview

Deciding whether any court has competence to deal with a case brought before it involves two questions:

- (1) Does this court have the power to deal with the subject-matter of the claim (subject-matter competence)?
- (2) Does this court have power to deal with the named defendant or defendants (personal jurisdiction)?

# **Subject-matter competence**

The types of action over which the Court has exclusive competence are listed in Article 32 UPCA. It should be noted that not all actions relating to patents come within this list. These exceptions include actions relating to licences, inventorship and employee inventions, for which the national courts have competence.

Article 32 UPCA Competence of the Court

The national courts retain competence for actions relating to national patents granted by the state where the court is located, and under the transitional regime of Article 83 UPCA.

#### Article 83 UPCA Transitional regime

#### Personal jurisdiction

The international jurisdiction of the Court is governed by the following legislation:

Article 31 UPCA International jurisdiction

(1) Regulation No. 1215/2012 (Brussels I recast) as amended by Regulation No. 542/2014 to deal, inter alia, with the UPC (Brussels I UPC), which governs issues of jurisdiction and enforcement of judgments within the EU, and;

Regulation No. 1215/2012 (Brussels I recast)

Regulation No. 542/2014 (Brussels I UPC)

(2) the Lugano Convention, which governs issues of jurisdiction and the enforcement of judgments between EU and EFTA countries other than Liechtenstein (namely Iceland, Switzerland and Norway).

#### **Basic rules**

- EU nationals can be sued in their EU state of domicile (Article 4(1) Brussels I recast).
- The ability to sue non-EU nationals depends on the national law of the state where the court is located (Article 4(2) Brussels I recast).
- For tort and related actions (including patent infringement), the place where the harm occurred will determine where the court is located (Article 7(2) Brussels I recast).
- For multiple defendants, the courts for the place where any one of the defendants are domiciled may be used, "provided claims are so closely connected that it is expedient to hear and determine them together to avoid the risk of irreconcilable judgments..." (Article 8(1) Brussels I recast).

#### Special patent rules

- An action relating to patent validity can only be brought in the courts of EU states where the patent is registered (Article 24(4) Brussels I recast).
- The UPC has jurisdiction as provided by the UPCA (Article 71b(1) Brussels I UPC).
- Non-domiciled defendants can be sued in the UPC if there is jurisdiction under Brussels I recast, and the court may award damages for infringements both outside and within the EU (Article 71b(2)(3) Brussels I UPC).
- The UPC can grant provisional measures, including protective measures, even if the courts in another state have jurisdiction over the subjectmatter (Article 71b(2) Brussels I UPC).

#### Competence of the divisions of the Court of First Instance

The central division has the general competence to deal with all Article 32 types of action for any defendant over whom there is personal jurisdiction, and exclusive competence where no local or regional division has competence.

Article 33 UPCA
Competence of the divisions of the Court
of First Instance

The parties may agree to bring any action (other than one concerning actions of the EPO) in any division, including the central division.

Article 33(7) UPCA

The competence of the local and regional divisions depends on the subject-matter of the action.

Article 33(1) UPCA

(1) Infringement, provisional relief, damages or compensation for use of an invention incorporated in a published application: action must be brought in the division where the infringement occurred or where the defendant lives or does business.

Multiple defendants must have a commercial relationship and be involved in the commission of the same alleged infringement.

Non-EU defendants must be sued in the division where infringement occurred or in the central division.

Once such an action is pending, no other division can accept an action between the same parties on the same patent.

If such an action is pending in a regional division and there is infringement in three or more regional divisions, the defendant can request transfer to the central division.

(2) Counterclaims for revocation may be brought in infringement actions in local or regional courts. That court may:

Article 33(3) UPCA

- Proceed with both and request to be allocated a suitable technically qualified judge.
- Refer the counterclaim to the central division and suspend or proceed with the infringement action.
- With the agreement of the parties, refer the whole case to the central division.
- (3) Declarations of non-infringement and actions for revocation must be brought:

Article 33(4) UPCA

- in the central division, unless
- there is an existing infringement action between the same parties for the same patent in another division.

If there is a pending revocation action in the central division, an action for infringement can be brought in the central division or any other competent division. If brought in a local or regional division, that division can proceed as in section 3 above.

Article 33(5) UPCA

An action in the central division for a declaration of non-infringement will be stayed if an infringement action between the same parties relating to the same patent is brought within three months in a local or regional division.

Article 33(6) UPCA

#### Territorial scope of decisions

Decisions of the UPC cover the territory of those contracting member states where the patent is in force.

Article 34 UPCA Territorial scope of decisions

#### Patent mediation and arbitration

Patent mediation and arbitration centres in Ljubljana and Lisbon will provide facilities in respect of patent disputes under the Agreement.

Article 35 UPCA
Patent mediation and arbitration centre

Any settlement reached via the facilities of these centres, including through mediation, is enforceable in the member states, and Article 82 UPCA will apply.

Patents may not, however, be revoked or amended in mediation or arbitration proceedings.

# **Financial provisions**

The budget of the UPC is financed by its own revenues (court fees and other fees) and – at least during the transitional period – by contributions from the member states.

Court fees consist of a fixed fee combined with a value-based fee, to be reviewed periodically.

Articles 36–39 UPCA
Budget of the Court
Financing of the Court
Financing of the training framework for judges
Financing of the Centre

# Organisation and procedural provisions

## Chapter I – General provisions

#### Statute and rules of procedure

The organisation and functioning of the Court is governed by the UPC Statute, which is annexed to the UPC Agreement.

Details of the Court procedure are contained in the Rules of Procedure (UPC Rules).

Article 40 UPCA
Statute

Article 41 UPCA
Rules of Procedure

## **General principles**

Litigation must be dealt with fairly, equitably and in a way which is proportionate to the importance and complexity of each case.

Article 42 UPCA
Proportionality and fairness

Cases must be actively managed in accordance with the Rules, but without impairing the parties' freedom to plead and prove their case. This includes the best use of electronic procedures.

Article 43 UPCA Case management

Article 44 UPCA
Electronic procedures

Proceedings must be open to the public, but the Court can, where necessary, make them confidential in order to protect the interest of any party or other affected person, or in the general public interest.

Article 45 UPCA Public proceedings

#### **Parties**

Any entity entitled to initiate proceedings under its national law has the capacity to be a party.

Article 46 UPCA Legal capacity

The following persons can bring proceedings:

Article 47 UPCA **Parties** 

- the patent proprietor;
- an exclusive licensee (unless not permitted to do so by the licence);
- a non-exclusive licensee, but only if permitted by licence and the proprietor is given notice;
- any person concerned with a patent who can bring an action under the
- any person who is affected by a decision of the EPO in relation to a unitary patent.

For actions brought by a licensee, the proprietor may join in the action. The validity of the patent can only be challenged if all the proprietors are parties. Where a counterclaim for revocation is brought against a claimant who is not the proprietor or not the sole proprietor, the Registry serves notice on the proprietor(s), who become parties to the revocation proceedings.

Article 47(4)(5) UPCA

Rule 25(2) **UPC** Rules

#### Representatives

Parties may be represented by either a lawyer authorised to practice before a court of a member state or a person qualified to act as a professional representative before the EPO (i.e. a European patent attorney) who also has a qualification approved by the UPC Administrative Committee to conduct litigation.

Article 48 UPCA Representation

Article 48(1) UPCA

Article 48(2)(3) UPCA

Article 48(4) UPCA

Representatives may be assisted by patent attorneys (not limited to European patent attorneys), usually for the provision of specialist technical expertise, who may be allowed to address the court in oral hearings. Patent attorneys are persons eligible to advise on patent protection in the state in which they practice.

Rule 287 6(b) UPC Rules Attorney - client privilege

#### Language of proceedings

#### **Court of First Instance**

#### Central division

Proceedings in the central division will be conducted in the language in which the patent was granted (i.e. English, French or German).

Article 49(6) UPCA Language of proceedings at the Court of First Instance

#### Local and regional divisions

The language used in local division proceedings will be the official language (or one of those languages, if there is more than one) of the state hosting that division. In a regional division, the states forming that division designate which EU official languages may be used. In addition, states may permit one or more of the EPO official languages to be used as a language of proceedings in their local or regional divisions.

Article 49(1) UPCA

Article 49(2) UPCA

#### Choosing the language

Where there is more than one designated language for the relevant court, the initial choice is made by the party who commences the proceedings. However, where the action is brought in a local or regional division against a defendant who has his domicile or principal place of business in the state concerned and who could not be sued in any other local or regional division, the proceedings must be conducted in the official language of that state. Where there are several regional languages which have been designated for that court, the language of the region where the defendant is located must be used.

Rule 14(2) UPC Rules Use of languages under Article 49(1) and (2) of the Agreement

Article 49(3) UPCA

The parties can agree to use the language in which the patent was granted, subject to approval by the panel hearing the case. Similarly, for convenience and fairness the panel may decide to use the language in which the patent was granted, provided the parties agree.

Article 49(4) UPCA

Article 49(5) UPCA

If there is disagreement on the language to be used, any of the parties can ask the President of the Court of First Instance to decide, after hearing representations, whether to use the language of the patent. The choice must be fair and take account of all the circumstances. The President must also assess the need for translation and interpreting.

#### **Court of Appeal**

Appeal proceedings will be in the language used in the proceedings before the Court of First Instance.

Article 50(1) UPCA Language of proceedings at the Court of

Parties can instead agree to use the language in which the patent was granted. If the appeal proceedings are in a different language from the first instance proceedings, the parties may be ordered to file translations of written pleadings and court orders.

Article 50(2) UPCA

Rule 232 UPC Rules Translation of file

In exceptional cases, the Court of Appeal can decide on another official language, provided the parties agree.

Article 50(3) UPCA

#### **Translation and interpreting**

For infringement proceedings in the Central Division, where the language of proceedings is not an official language of the state of the defendant's

Article 51(3) UPCA Other language arrangements residence or place of business and the defendant does not have sufficient knowledge of the language of proceedings, the defendant has the right to request translation of the relevant documents.

Where a revocation action is transferred to the Central Division, the parties may be ordered to supply a translation of the pleadings in the local or regional division.

**Rule 39 UPC Rules** Language of the proceedings before the central division

A party can request simultaneous interpretation of oral hearings by written application made at least a month before the hearing date, giving the information required by the Rules. The judge-rapporteur decides if, and to what extent, simultaneous interpretation is required, and may also independently order interpretation. The costs of interpretation provided by the court are part of the costs of the proceedings. A party may arrange for its own interpreter, in which case the costs are borne solely by that party.

Rule 109 UPC Rules Simultaneous interpretation during oral hearings

#### **Proceedings before the Court**

#### Written, interim and oral procedures

The proceedings before the Court of First Instance and the Court of Appeal consist of a written procedure, an interim procedure and an oral procedure. Details are set out in the Rules of Procedure.

In the first stage, the parties will exchange written briefs. The exchange of written pleadings and briefs is the basis for the decision of the Court to be taken at the end of the proceedings. In infringement actions there will typically be two rounds of exchange of briefs, starting with a statement of claim and a statement of defence by the defendant. A second round will comprise the reply to the statement and a rejoinder to that reply. As a counterclaim the defendant may also file a petition for revocation of the patent. In this case, the claimant and any proprietor becoming a party to the lawsuit must also lodge a defence to that counterclaim. Optionally, also with regard to the counterclaim, a reply and a rejoinder may be possible.

In the written briefs, the parties must present their arguments, the underlying facts and the evidence in support of the facts as completely as possible. Certain formalities must be observed. One of the main issues is the clarity of the allegations and the counterclaim (if any). The purpose of the written procedure is to prepare for the next steps in the proceedings. The rules for different kinds of action (infringement, revocation, declaration of non-infringement or licencing disputes are very similar and follow the same path.

Article 52 UPCA Written, interim and oral procedures The aim of the interim procedure which follows the written procedure is to explore the possibility of a settlement, which might also be achieved by way of mediation and/or arbitration. The responsibility for this lies with the Judge Rapporteur. During the interim procedure, an interim conference is held in which the Judge Rapporteur discusses the details of the proceedings with the parties. The aim of the conference is to identify the critical aspects of the case, both with regard to legal and factual aspects and to prepare the oral hearing if no settlement can be reached. In that case, the Court will issue a summons to the oral hearing.

The proceedings end with an oral hearing (oral procedure), which is held before the full panel of judges. The Presiding Judge presides over the hearing. A preliminary introduction may be given by the Court, followed by the parties presenting their arguments. The Court may also hear witnesses or experts where necessary. Also, the parties may put questions to the witnesses or experts. Hearings should normally be completed in a day.

Following the hearing, the Court renders its decision on the merits.

The determination of damages and compensation as well as a decision on costs may be dealt with at a separate hearing.

# **Provision of evidence**

Evidence may be provided in a variety of ways. The UPC contains a nonexhaustive list, including the hearing of parties and witnesses, requests for information, the production of documents, expert opinions and sworn statements in writing (affidavits).

Again, details are set out in the Rules of Procedure. As a matter of principle, evidence should be provided by the parties as early as possible in the proceedings.

# **Burden of proof**

The general rule is that the burden of the proof of facts lies with the party relying on those facts. This is an established principle in many jurisdictions. In other words, the risk of not being able to produce sufficient evidence for a fact which has been legitimately contested by the other party lies with the party which has presented the fact in order to support its position.

As a result, a decision cannot be based on a fact which has been contested and for which there is not sufficient evidence to meet the required standard.

Article 53 UPCA Means of evidence

Article 54 UPCA Burden of proof In certain cases, there may be exceptions to this general principle, and the burden of proof may be reversed and shift to the other party. This includes cases where the subject-matter of a patent is a process for obtaining a new product. Here an identical product will be deemed to have been obtained by the patented process, and the defendant will have to prove the contrary.

Article 55 UPCA Reversal of burden of proof

The same principle applies where there is a substantial likelihood that the product was made by the patented process and the patent proprietor has made all reasonable efforts to establish the process which was actually used for making such identical product. In this context, the provision of evidence mentioned above must be observed. This includes any inspection orders made by the Court.

In any event, where the burden of proof is reversed, the legitimate interests of the defendant in protecting his own manufacturing and trade secrets must be taken into account. Consequently, the reversal of the burden of proof may not require the defendant to reveal legitimate secrets to the other party. In which case, the lack of proof or evidence may not be held against the defendant to his disadvantage.

### **Powers of the Court**

# Introduction

The powers of the Court comprise the measures, procedures and remedies as laid down in the UPCA. They concern the conduct of effective proceedings in compliance with the Rules of Procedure, orders, and interim and final decisions on the merits of a case. In this context, the Enforcement Directive<sup>11</sup> is the minimum standard for the interpretation of the provisions in the UPC Agreement (see Article 20 above and the Preamble to the UPCA).

Article 56 UPCA The general powers of the Court

The chapter of the UPCA dealing with the powers of the Court also concerns the remedies available to the parties involved. It should be noted that only a few measures and remedies are compulsory, whereas on the other hand there is a wide discretion for the Court to exercise its powers.

# **Procedural powers**

The Court will guide the proceedings. It has been given sufficient powers to manage them efficiently. In order to obtain the necessary expertise, it may at any time appoint Court experts with regard to specific aspects of the case. These experts serve as independent experts and provide the Court with additional evidence.

Article 57 UPCA **Court experts** 

<sup>11</sup> Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights; OJ of 2 June 2004 L195/16.

One important aspect is the protection of trade secrets and other confidential information belonging to the parties. As a general rule, the Court may order that the collection and use of evidence in proceedings before it be restricted or prohibited or that access to such evidence be restricted to specific persons. Such an order will ensure that, even if certain evidence is admitted, additional trade secrets of the party producing the evidence may be protected and will be exempt it from file inspection or other access by third parties. In practice, this may come close to the protective orders known from US and UK proceedings.

Article 58 UPCA Protection of confidential information

This is particularly important in view of the fact that the Court will also have the power to order the opposing party or a third party to present evidence where a party to the proceedings has presented reasonably available evidence which is sufficient to support the claims and has specified evidence which lies in the control of the opposing party or a third party. This includes banking, financial and commercial documents.

Article 59 UPCA Order to produce evidence

The Court will also be able to issue orders to preserve evidence. It will be in a position to take prompt and effective provisional measures, including a detailed description, taking samples and the physical seizure of the infringing products or materials and items used in the production of such products. Such measures may be taken before proceedings on the merits have started. Such an order may also be issued ex parte, i.e. without the other party having been heard. As a prerequisite, the applicant must present some evidence to support the claim that the patent has been infringed or is about to be infringed. The level of that evidence is not stated in either the UPCA or the Rules of Procedure and will have to be determined by the case law of the Court in due course.

Article 60 UPCA Order to preserve evidence and to inspect premises

The Court may also issue so-called "freezing orders". These orders prohibit parties from removing any assets from the jurisdiction of the Court or from dealing in such assets. They secure financial assets but are not linked to preserving items or producing evidence.

Article 61 UPCA Freezing orders

Where measures to preserve evidence or freezing orders are revoked or set aside or where no infringement or threat of infringement has been proved, the Court may order the applicant to provide the defendant with appropriate compensation for any damage suffered as a result of imposing those measures.

Article 60(9) UPCA Order to preserve evidence and to inspect premises

# Provisional and protective measures

In patent practice, provisional measures are of great importance. The Court may, by order, grant injunctions against alleged infringing parties to prohibit the continuation of the alleged infringement. Alternatively, it may make the continuation of the alleged infringing acts subject to the lodging of guarantees which would serve to secure the compensation of

Article 62 UPCA Provisional and protective measures the successful patentee at a later stage. These orders are subject to the discretion of the Court and may be made depending on the circumstances of the case concerned.

What is particularly important in this context is that the UPCA contains guidelines on the exercise of discretion by the Court. Accordingly, the Court may weigh up the interests of the parties involved and may in particular take into account the potential harm for either of the parties resulting from the granting or refusal of a provisional injunction ("balance of convenience").

Also, as a provisional measure, the Court may order the seizure or delivery up of products suspected of infringing and the precautionary seizure of property belonging to the alleged infringer to secure the recovery of potential damages.

With regard to provisional measures, there is also guidance as regards the standard of proof. A provisional injunction will most likely be granted only if there is satisfactory evidence for the Court to find a degree of certainty as regards the alleged infringement.

Also, with regard to provisional injunctions, the Court may order the claimant to provide the defendant with appropriate compensation for damages suffered as a result of those measures if the injunction is subsequently revoked ("cross-undertaking as to damages").

# **Permanent injunctions**

Where the Court holds a patent to be infringed, it may grant an injunction against the infringer prohibiting the continuation of the infringement. The wording of the UPCA leaves it to the Court to decide whether or not to grant an injunction. This is a somewhat new concept in comparison with the traditional view in Europe, where it would be almost automatic for infringement to be prohibited by injunction.

Nevertheless, it should be noted that it is thought that the Court's discretion should be exercised in such a way that an injunction will as a general rule be granted. The wording of Article 63 UPCA, however, opens up the possibility for the Court to take into consideration all the circumstances of the case, so that - as an exception to the general rule - an injunction might be denied even though infringement has been established.

Where appropriate, non-compliance with an injunction will be subject to a recurring penalty, payable to the Court. Under the UPCA, penalties (or fines) cannot be paid to the claimant or patentee.

Article 63 UPCA Permanent injunctions

### **Corrective measures**

The Court will also have the discretion to order corrective measures, such as a declaration of infringement, the recall of products, the removal of products from the channels of commerce, or the destruction of infringing products.

Article 64 UPCA Corrective measures in infringement proceedings

Such measures will be ordered without prejudice to any damages which the injured party may claim. They will reflect the need for proportionality between the seriousness of the infringement and the remedies to be ordered, and the willingness of the infringer to modify the infringing material so that it no longer infringes.

# Decisions on the validity of patents

The Court also has the power to decide on the validity of a patent. It will have to take such decisions when an alleged infringer files a counterclaim for revocation or in independent revocation actions.

The Court may revoke a patent only on the grounds laid down in Articles 138(1) and 139(2) EPC. Limitation by way of amendment of the claims in accordance with the provisions of the EPC is possible. This may lead to a revocation of the patent in part only. As a result, and to the extent that the patent has been revoked, it will be deemed to have had no effect from the date of grant.

A copy of the decision will be sent to the EPO and the relevant national patent offices.

# Award of damages and communication of information

The Court will order an award of damages where the infringer has knowingly, or with reasonable grounds for knowing, engaged in an infringing activity, in which case damages are compulsory. The injured party should be placed in the position it would have been in if no infringement had taken place. Damages will not be punitive.

The actual amount of the damages is to be calculated taking into account all relevant circumstances, in particular any negative economic consequences, including lost profits suffered by the injured party and unfair profits made by the infringer. As an alternative, damages may also be set as a lump sum on the basis of the amount of royalties or fees which would have been due if the infringer had requested a licence to use the patent.

Even where the infringer did not knowingly, or with reasonable grounds to know, engage in the infringing activity, the Court may order the recovery of profits or the payment of compensation.

Article 65 UPCA
Decision on the validity of a patent

Article 68 UPCA Award of damages

Article 67 UPCA
Power to order the communication of information

The infringer may also be ordered to provide in detail information such as the origin and the distribution channels and quantities of the infringing goods as well as the prices obtained for the products and/or the identity of third persons involved in the infringement. This information will serve as a tool for the right holder to calculate damages or to pursue his rights against further infringing parties other than the defendant.

# **Legal costs**

As a general rule, the unsuccessful party must bear the reasonable and proportionate legal costs and other expenses incurred by the successful party.

Article 69 UPCA Legal costs

### Period of limitation

Any claims for financial compensation must be brought before the Court no later than five years after the applicant becomes aware, or has reasonable grounds to become aware, of the last fact justifying the action.

Article 72 UPCA Period of limitation

### **Appeals**

Decisions of the Court of First Instance are subject to appeal. An appeal may be brought before the Court of Appeal by a losing party.

Article 73 UPCA Appeal

As with the Court of First Instance, the procedures before the Court of Appeal comprise a written procedure, an interim procedure and an oral procedure, followed by the decision of the Court.

The statement of appeal must be filed within two months after service of the Court of First Instance decision. Within four months of the same date, a statement of grounds of appeal must be filed which must contain an indication of which parts of the decision are contested, the reasons therefor and an indication of the facts and evidence on which the appeal is based. These may be points of law and matters of fact. New facts and new evidence may only be introduced into the appeal proceedings where such material could not reasonably have been made available during proceedings before the Court of First Instance.

The Court of Appeal will examine the facts and any points of law and will review the case de novo. The proceedings follow the same rules as the proceedings before the Court of First Instance.

In its decision, if the appeal is well-founded, the Court of Appeal must revoke the decision of the Court of First Instance and give a final decision. In exceptional cases, the case may be referred back to the Court of First

Article 75 UPCA Decision on appeal and referral back Instance, which will then be bound by the decision of the Court of Appeal on points of law.

Under certain circumstances the Court of Appeal may also by way of exception grant a request for rehearing after a final decision has been taken by the court. In that case, the proceedings will be reopened for a new hearing and decision.

Article 81 UPCA Rehearing

Generally speaking, an appeal will not have suspensive effect, unless the Court decides otherwise at the request of one of the parties. An appeal against a decision regarding invalidity of a patent will always have suspensive effect.

Article 74 UPCA Effects of an appeal

A party who has not lodged an appeal in due time may nevertheless file a statement of cross-appeal as part of its statement of response to the appeal of the other party. The rules for appeal apply mutatis mutandis to cross-appeals.

**Rule 237 UPC Rules** Statement of cross-appeal

### **Decisions**

Decisions must be taken in accordance with the requests of the parties. The Court may not award more than is requested. Decisions may be based only on grounds, facts and evidence which were the subject of the proceedings and to which the parties had an opportunity to respond.

Article 76 UPCA Basis for decisions and right to be heard

Further details of the formal requirements can be found in the Rules of Procedure. While decisions must be taken by a majority of the panel, any judge of the panel may, in exceptional circumstances, express a dissenting opinion separately from the decision of the Court.

Article 77 UPCA Formal requirements

A decision on the merits of an infringement claim may be rendered on condition that the patent is not held invalid (wholly or partially) by the final decision in the revocation procedure or by a final decision of the EPO or under any other term or condition if a revocation action is pending in parallel between the same parties before the central division or if an opposition is pending before the EPO.

Article 78 UPCA Decisions of the Court and dissenting opinions

In addition to the proceedings being public, the Court may order that information about the decision be published at the expense of the infringer, including its publication in full or in part in public media.

Article 80 UPCA **Publication of decisions** 

The parties may notify the Court that they will not be represented at the oral hearing. In that case, their written submissions will be taken into consideration. However, the Court may also give a decision by default if a duly summoned party fails to appear at an oral hearing without

notification. Such a decision by default against the defendant may only be given where the facts put forward by the claimant justify the remedy sought.

Decisions of the Court are enforceable in any contracting member state. The enforcement may be subject to the provision of security for potential damages suffered, in particular in the case of injunctions. Noncompliance with the terms of an order of the Court may be sanctioned with penalties payable to the Court.

Article 82 UPCA **Enforcement of decisions and orders** 

# **Transitional provisions**

Article 83 UPCA provides for a transitional period of seven years, which can be extended by up to seven more years (Article 83(5)).

Article 83 UPCA Transitional regime

There are basically two transitional schemes.

# (1) Concurrent jurisdiction

During the transitional period, there will be a concurrent jurisdiction of the UPC and the national courts in respect of the classic European bundle of patents. In other words, during that time, patent proceedings in respect of (national tiers of) European patents may be brought before the national courts or the UPC, at the choice of the claimant. This does not apply to unitary patents.

The Agreement states that only infringement or revocation claims can still be brought before the national courts. It is, however, the majority view that this must in fact cover all types of dispute in respect of European patents falling under the exclusive jurisdiction of the UPC after the transitional period (listed in Article 32(a) UPCA).

Also, this concurrent jurisdiction may give rise to issues of *lis pendens* under Brussels I Recast, under which the subsequently seized court may – or in some cases must – stay the proceedings until the first seized court has rendered a decision.

Regulation (EU) No 1215/2012, as amended; see in particular Articles 71a-71d and 29-32

# (2) Opt-out

Proprietors of or applicants for a classic European patent can opt out of the UPC's exclusive jurisdiction. An opt-out can later be withdrawn.

However, once litigation has been initiated in one system or the other, this fixes the European patent/application in said system. In other words, if an action is started before the UPC, an opt-out is no longer available. Likewise, an action before a national court precludes the proprietor/applicant from withdrawing the opt-out at a later stage.

Opt-outs must be notified to the Registry, with the opt-out taking effect upon the date the entry is recorded in the Register. In order to ensure that there is sufficient time to enter the initial opt-outs in the Registry, the Rules of Procedure provide for a sunrise period prior to the entry into force of the UPC.

The majority view is that the opt-out option will apply throughout the entire life of the patent (and not just during the transitional period), and to all designations under the European patent (not country by country).

It is not possible to opt out of a unitary patent.

# **Final provisions**

The UPCA is open to accession by all EU member states, following the procedure set out in Articles 84–85.

It is of unlimited duration (**Article 86**), and can be revised to bring it into line with relevant international treaties or if deemed necessary after the broad consultation with the users of the patent system scheduled to take place after seven years or 2 000 infringement cases, whichever is later (**Article 87**).

The original languages of the UPCA are English, French and German. Approved versions in other official languages of the contracting member states are also official texts. However, in the event of divergences, the three original languages will prevail.

# **Entry into force**

The UPCA will enter into force on the first day of the fourth month following its ratification by 13 member states, including France, Germany and the UK (the three countries where most European patents have effect).

Article 84 UPCA
Signature, ratification and accession

Article 85 UPCA Functions of the depositary

Article 86 UPCA
Duration of the Agreement

Article 87 UPCA Revision

Article 88 Languages of the Agreement

Article 89 UPCA Entry into force



# THE UNITARY PATENT AND THE UNIFIED PATENT COURT

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# **ABBREVIATIONS**

CJEU	Court of Justice of the European Union
CMS	Case Management System
EP	European Patent
EPC	European Patent Convention
EU	European Union
MS	Member State of the European Union
PPA	Protocol for Provisional Application
SPC	Supplementary Protection Certificate
UPC	Unified Patent Court
UPCA	Unified Patent Court Agreement
UP	European patent with unitary effect or Unitary Patent

### **OVERVIEW**

# Why This Is Important— In a Nutshell

- The introduction of the Unitary Patent (UP) and the Unified Patent Court (UPC) is the most significant development in patent enforcement in Europe for a generation. The new system will be a fundamental change in the international patent landscape and is likely to have a considerable impact on global patent strategy.
- It will create a new patent right, the Unitary Patent, which will provide a single patent right providing protection across all of the participating Member States.
   The UP will exist alongside existing national patents in European territories as well as standard European bundle patents (EP) which are separately validated in European Patent Convention (EPC) territories.
- A key objective of the UP (and UPC) is to reduce costs for patentees. There will be almost no translation costs for the UP and a single relatively low renewal fee (roughly corresponding to total fees payable for renewing EPs in 4 to 5 EU countries).
- The UPC is designed to streamline patent litigation across Europe. It will be an entirely new international patent court, which will be a single patent court with jurisdiction in at least 17 participating Member States (and potentially up to 24 States of the European Union in due course). This will make it, on some measures the largest patent litigation forum in the world.
- The UPC will have exclusive jurisdiction over administrative issues and disputes involving a UP. It will also have concurrent jurisdiction with national courts to handle patent disputes involving an EP for a transitional period of 7 years (which may be extended up to 14 years), unless the EP is explicitly opted out of the system. After the transitional period, the UPC will also have exclusive jurisdiction over EPs in the participating EU Member States. Only national patents will remain outside the jurisdiction of the UPC.

# Participating Member States

- Not all 38 countries that are parties to the EPC can be part of the new UP / UPC. Only EU Member States can participate, which excludes, inter alia, the UK and Switzerland. In addition, three of the 27 EU Member States have declined to participate in the UPC (Spain, Poland, and Croatia).
- Participation requires signing and ratifying a treaty for establishing the Unified Patent Court (the Unified Patent Court Agreement or UPCA) and the Protocol for Provisional Application (PPA). The following chart lists the Member States that are on their way to such ratifications.

UPC Member States (MS)	UPCA Ratification*	PPA Ratification*
AT, BE, BG, DK, EE, FI, FR, IT, LU, NL, SE, SI	(16 MS)	(12 MS)
LT, LV, MT, PT		(4 MS)
DE	(1 MS)	(1 MS)
CZ, IE, GR, CY, HU, RO, SK	(7 MS)	

<sup>\*</sup>Status May 2022

- The UPCA will enter into force on the first day of the fourth month after 13 of the Participating Member States have ratified the UPCA (including the ratifications by France, Germany and Italy).
- Germany has voluntarily stayed the deposit of its instrument of UPCA ratification until the UPC is ready for operation.
- Additional EU Member States can ratify the UPCA after the UPCA has entered into force.
- The territorial scope of a UP is limited to the countries that have ratified the UPCA at the date of registration that this patent is to have unitary effect (see further below).

# Participating Member States

EPC N	MEMBER STATES	RATIFICATION OF UPCA	PARTICIPATION IN THE UP AND UPC
AL	Albania		Not an EU Member State
ΑТ	Austria	<b>Ø</b>	Yes
BE	Belgium	<b>Ø</b>	Yes
3G	Bulgaria		Yes
ΗR	Croatia	Not signed after joining the EU in 2013	Still possible
CY	Cyprus	Signature only	Not yet
CZ	Czech Republic	Signature only	Not yet
ΣK	Denmark	<b>Ø</b>	Yes
EE	Estonia	<b>Ø</b>	Yes
=1	Finland	<b>Ø</b>	Yes
R	France	<b>Ø</b>	Yes
DE	Germany	<b>⊘</b>	Yes
	Germany	(not yet deposited)	
GR	Greece	Signature only	Not yet
HU	Hungary	Signature only	Not yet
S	Iceland		Not an EU Member State
E	Ireland	Signature only	Not yet
Т	Italy	<b>Ø</b>	Yes
_V	Latvia	<b>Ø</b>	Yes
.I	Liechtenstein		Not an EU Member State
Т	Lithuania	<b>Ø</b>	Yes
_U	Luxembourg	<b>Ø</b>	Yes
ИK	Macedonia		Not an EU Member State
ИΤ	Malta	<b>⊘</b>	Yes
ИС	Monaco		Not an EU Member State
۱L	Netherlands	<b>Ø</b>	Yes
10	Norway		Not an EU Member State
PL	Poland	NO	DECLINED
PT	Portugal	<b>Ø</b>	Yes
RO	Romania	Signature only	Not yet
SM	San Marino		Not an EU Member State
RS	Serbia		Not an EU Member State
SK	Slovakia	Signature only	Not yet
SI	Slovenia	<b>Ø</b>	Yes
S	Spain	NO	DECLINED
SE	Sweden	<b>Ø</b>	Yes
CH	Switzerland		Not an EU Member State
ΓR	Turkey		Not an EU Member State
JK	United Kingdom	Withdrawn	Not an EU Member State
	38	17 (out of 24 UPCA signator	

(Status: May 2022)

# The New Patent Map for Europe



# Features of a UP

- A UP will be a single patent based on a granted EP and will have effect in the territories of the countries that have ratified the UPCA at the date of registration of unitary effect. Given that ratifications of the UPCA will likely take place successively over time, there will be different generations of UPs with different territorial coverage. A UP will be a single indivisible patent right. This means that it will not be possible to allow a UP to selectively lapse in one or more territories while maintaining protection in others.
- A UP will not cover all EPC Member States as some countries including the UK, Spain, Poland and Switzerland, are not going to be in the system. Patent protection in these territories will continue to be available through existing validation procedures of standard EPs or via national patent filings.
- The territorial coverage of a UP will remain constant for its entire lifetime. This means that, for instance, a given UP's territorial coverage will not be extended to other EU Member States that ratify the UPCA after the registration of its unitary effect. However, divisional UPs may have different territorial scope compared to the parent UP due to the later date of registration of the divisional patent's unitary effect.
- The UP may provide patentees with broader coverage than they would have pursued under the current EP system. Previously some of the UP countries may not have been considered for EP validation due to the additional expense.
- There are however certain potential downsides of a UP. Of these, the most significant is the risk of central revocation of a UP across all jurisdictions at any time during the life of the patent (presently, EPs can only be centrally revoked following a challenge during the 9-month opposition period following grant).
- A UP can be enforced and challenged only though the UPC.
- The seat/place of business of the first named applicant will determine the applicable law for the UP as an object of property.

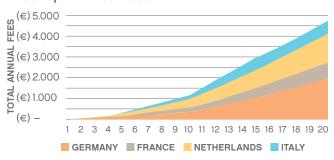
# Grant Procedure and Registration of Unitary Effect

- UPs are granted by the European Patent Office (EPO) in the course of the existing EP grant procedure.
- Once the UPCA enters into force, the applicant will be able to choose whether or not the resulting EP should have 'unitary effect' in the contracting EU Member States. Such a request has to be filed within one month of a decision to grant. In the absence of such a request, the application will lead to the grant of a standard EP, requiring validation in each designated state in the usual way.
- A request for unitary effect can only be made in respect of EPs that are granted with the same set of claims for all UP participating Member States.
- If the EPO determines that at least one of the formal requirements for the request for unitary effect is not met, it will invite the applicant to correct the deficiencies within a non-extendable period of one month. The request will be rejected if the deficiencies are not addressed within this period. Applicants will have the right to appeal the decision of the EPO to the UPC.

# Costs and Patent Renewal Fees

- A UP will be subject to a single renewal fee which will be payable to the EPO.
- The EPO will retain approximately 50% of the renewal fees. The remainder will be distributed between the participating Member States.
- The renewal fees for UPs have been set at a "True top
  4" level, meaning that they would be equivalent to the
  total renewal fees payable for the four most validated
  countries for standard EPs (namely, Germany, France,
  Netherlands and Italy). This means that significant
  cost savings are possible relative to standard EPs for
  obtaining coverage in up to 24 countries.
- Renewal fees are reduced by 15%, if patent holder registers a license of right.

# "True Top 4" Annual Fees



# Patent Renewal Fees

PATENT YEAR	UNITARY PATENT*	TRUE TOP FOUR**	ALL 24 UPC MEMBER STATES***	ALL 38 EPC MEMBER STATES***
1	_	_	180	330
2	35	38	218	461
3	105	108	1,335	1,879
4	145	148	1,765	2,559
5	315	288	2,396	3,457
6	475	456	3,111	4,382
7	630	616	3,713	5,197
8	815	826	4,455	6,222
9	990	1,010	5,375	7,390
10	1,175	1,200	6,261	8,608
11	1,460	1,540	7,304	10,035
12	1,775	1,930	8,420	11,617
13	2,105	2,340	9,599	13,211
14	2,455	2,710	10,764	14,779
15	2,830	3,070	11,914	16,340
16	3,240	3,400	13,272	18,297
17	3,640	3,740	14,594	20,150
18	4,055	4,090	15,826	21,942
19	4,455	4,440	17,365	24,105
20	4,855	4,790	18,842	26,157
Total (€)	35,555	36,740	156,709	217,118

<sup>\*</sup> Unitary Patent fees as of May 10, 2022 (EPO); all in €

<sup>\*\*</sup> Total renewal fees in DE, FR, NL and IT; all in €

<sup>\*\*\*</sup> Total renewal fees as of May 10, 2022 (EPO); all in €

# Comparison: National Patent Renewal Fees

PATENT YEAR	DE	UK	FR	NL	IT
1	_	_	-	_	_
2	_	-	38	_	_
3	70	_	38	_	_
4	70	_	38	40	_
5	90	82	38	100	60
6	130	105	76	160	90
7	180	129	96	220	120
8	240	152	136	280	170
9	290	175	180	340	200
10	350	199	220	400	230
11	470	222	260	500	310
12	620	257	300	600	410
13	760	304	350	700	530
14	910	351	400	800	600
15	1,060	421	460	900	650
16	1,230	491	520	1,000	650
17	1,410	550	580	1,100	650
18	1,590	608	650	1,200	650
19	1,760	666	730	1,300	650
20	1,940	713	800	1,400	650
Total (€)	13,170	5,425	5,910	11,040	6,620

Renewal fees as of May 10, 2022 (EPO); all in €

# Applicable Law

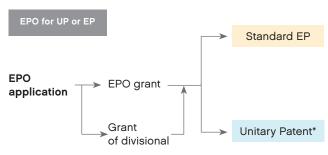
- The rights conferred by a UP (e.g., definition and consequences of infringement) are the same for all participating Member States, as they are stipulated in the UPCA itself.
- The UP will be governed by the law of one of the participating Member States (e.g., conditions for co-ownership, transfer of ownership and priority rights) and applies to the UP in its entirety.
- Applicable law is determined by reference to the law governing the UP as an object of property, which is defined as the law of the participating Member State where, at the time of filing of the patent application:
  - The applicant had its residence or principal place of business, or, in absence of this, any place of business:
  - For joint applicants (co-owners), the first listed applicant is decisive;
  - 3. If none of the applicants matches these conditions, then, by default, **German law** will apply.

# Language and Translation Requirements

- A key underlying objective of the UP is to simplify existing language and translation requirements for European patents. The ultimate intention is that:
  - There will be no formal translation requirements for the UP in the long run;
  - 2. The EPO's free online machine translation program will be used primarily for translations; and
  - A full human translation will only need to be provided in case of dispute, at the request of the Court or the request of an alleged infringer.
- Language requirements of the grant proceedings before the EPO remain the same.
- There will be a transitional period (6 to 12 years) until high quality machine-translation tools are available.
   During the transitional period, a translation of the description and claims will be required:
  - 1. Filing in German: English translation;
  - 2. Filing in French: English translation;
  - Filing in English: translation into any official EU language.
- Translation requirements will change after the transitional period.
- There is no language regulation for opt-out declarations during the three-month "sunrise period" immediately preceding the entry into force of the UPC. It is advisable to use the language of the patent application.

# Patent Filing and Prosecution Options

- After EPO grant, the applicant can choose to obtain a UP or a standard EP. After grant of a divisional application, there is the renewed choice of obtaining a UP or a standard EP.
- Geographical scope of protection of a UP depends on the UP participating Member States at the date of registration of unitary effect. Filing European divisional applications with different or broader geographical coverage and/or scope of protection may be considered - some to be opted out, some to remain in the UPC.



\*non-participating Member States via standard EP.

 Direct national patent filings may be considered when protection is sought in only a small number of countries.

# National Application DE application → DE grant → DE FR application → FR grant → FR IT application → IT grant → IT

 Alternative protection by national utility models/utility certificates/short-term patents derived from a EP, UP or PCT may be considered. Such protections are available in some EU Member States, such as Austria, Bulgaria, Czech Republic, Germany, Denmark, Estonia, Spain, Finland, France, Greece, Croatia, Italy, Hungary, Poland, Portugal, Romania, Slovakia.

# Patent Filing and Prosecution Strategies

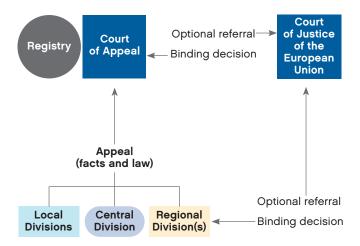
- · Various parallel protections are possible:
  - Parallel protection from a national part of an EP and a national utility model or certificate/shortterm patent is possible in states such as: Austria, Bulgaria, Croatia, Czech Republic, Denmark, Germany, Estonia, Finland, France, Hungary, Poland, Portugal, Romania, and Slovakia.
  - Parallel protection from a EP and a direct national patent is possible in states such as: Austria,
     Denmark, Finland, Hungary, Iceland, Norway,
     Poland, Portugal, and Sweden.
  - Parallel protection from a direct national patent and either a not-opted-out EP or a UP is possible in states such as: France and Germany.
- Applicants will need to carefully consider prosecution strategies in light of the new system. For instance, if unitary protection is desirable for a pending EP application that is currently nearing grant stage, it may be appropriate to consider strategies to delay grant (e.g. by filing amendments or requests for further processing). In the alternative, the applicant may wish to file an early request for unitary effect. In this regard, it is notable that the EPO will allow such requests in respect of pending EPs from the date on which the UPCA comes into force. An early request for UP may be filed once an intention to grant has been issued by the EPO. However, filing such an early request for unitary effect does not imply that the EPO will delay issuing the decision to grant an EP, so that such request will be ineffective if the EP is granted before the UPCA enters into force.
- To mitigate this transitional situation, the EPO also allows the applicant, from the date Germany ratifies the UPCA until the UPCA enters into force (the three-month "sunrise period"), to request a delay in the issuance of the decision to grant in pending EP applications. This applies in situations where the communication of intention to grant has been issued, but the applicant has not yet approved the text intended for grant.

# Key Facts in Brief

- The UPC is an entirely new court with newly created procedural rules.
- The UPC is international and completely independent from any national court.
- The UPC has jurisdiction solely for patent litigation, but handles both infringement and (in)validity proceedings.
- The UPC is a "closed" court system. Patent cases will be finally decided by the UPC, with the possibility of referrals to the Court of Justice of the European Union (CJEU) on certain matters of law.
- The UPC blends procedural rules and customs from various European jurisdictions. Case law of the UPC on substantive law issues will need to develop over time and this may end up incorporating practices and approaches from various European jurisdictions.
- The UPC provides a unified court for participating Member States instead of the existing patchwork of patent courts. There will be one decision for the entire UPC territory.
- The UPC has exclusive jurisdiction over UPs.
- During the transitional period of 7 years (and up to possibly 14 years), the UPC will also have joint jurisdiction with the national courts over already granted EPs, unless the EP is explicitly opted out. The UPC will assume exclusive jurisdiction over EPs after the transitional period.
- The UPC has various Divisions (Central, Regional, Local divisions) among which the plaintiff is able to choose the venue for the first instance proceedings.
- There will be potential for forum shopping within the UPC and between the UPC and national courts.

# Structure of the Unified Patent Court

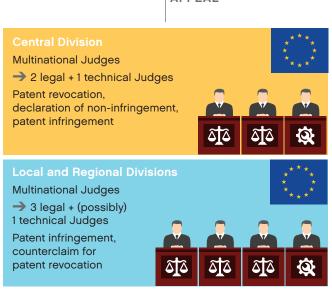
- The UPC comprises the Court of First Instance and the Court of Appeal.
- The Court of First Instance consists of:
  - Local Divisions typically, one per larger Member State:
    - Germany will have four (Düsseldorf, Munich, Mannheim and Hamburg);
    - Single Local Divisions are expected in Austria, Belgium, Denmark, Finland, France, Italy, the Netherlands, Portugal and Slovenia.
  - 2. Regional Divisions for groups of Member States without their own Local Divisions:
    - Sweden and the Baltic States will host a Regional Division for Sweden, Latvia, Lithuania and Estonia.
  - 3. The **Central Division** will have its seat in Paris and a section in Munich.
- · The Court of Appeal is located in Luxembourg.
- Either instance may refer selective questions of law to the CJEU, also located in Luxembourg.



# Composition of the Panels of the Court

- Judges are recruited from various jurisdictions across Europe.
- Each panel will consist of judges from at least two countries.
- Panels will comprise legally qualified judges of mixed nationality.
- Some Court panels will include technically qualified judges.
- Legally and technically qualified judges will have equal voting rights.





# Competence of the Unified Patent Court

- From the day the UPC becomes operational, it will have exclusive jurisdiction for the following actions relating to UPs and, subject to a transitional period and possible opt-out, relating to standard EPs and Supplementary Protection Certificates (SPCs):
  - o actions for infringement;
  - o actions for declarations of non-infringement;
  - actions for provisional and protective measures and injunctions;
  - actions for revocation of patents and for declaration of invalidity of SPCs;
  - o counterclaims for revocation;
  - o action for damages or compensation;
  - actions relating to the use of the invention prior to the granting of the patent or to the right based on prior use of the invention;
  - actions for compensation for licenses of right of UPs;
  - Decisions of the EPO in carrying out the administrative tasks regarding UPs.
- All other actions are outside the jurisdiction of the UPC and thus remain within the exclusive jurisdiction of national courts, notably:
  - o actions concerning national patents;
  - o claims regarding ownership;
  - ° remuneration of employees' inventions;
  - ° contractual claims.
- During a transitional period of 7 years (possibly extended to 14 years), actions for infringement or for revocation of an EP or an SPC may still be brought before national courts.

# Subject Matter Competence of the Central Division Sections

PC CLASS	SUBJECT MATTER	ASSIGNED TO
Α	HUMAN NECESSITIES	To be relocated
В	PERFORMING OPERATIONS; TRANSPORTING	Paris
С	CHEMISTRY; METALLURGY	To be relocated
D	TEXTILES; PAPER	Paris
E	FIXED CONSTRUCTIONS	Paris
F	MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING	Munich
G	PHYSICS	Paris
Н	ELECTRICITY	Paris

# Procedure before the UPC

- The UPC aims to have a first instance hearing on infringement and validity within one year of the issuance of the claim.
- The UPC Rules provide for a three-stage procedure:
  - Written procedure: A key feature is the exchange of detailed pleadings in the early stages of the proceeding which is designed to "to front-load" the legal arguments and evidence and facilitate early resolution. This is similar to existing European civil-law litigation procedure.
  - Interim procedure: The reporting Judge will have responsibility for actively preparing and managing the case for the oral hearing, clarifying selected issues and deciding on document production, etc.
  - Oral procedure: In most cases, there will be a one-day hearing and in simpler cases, this may be followed by a decision on the same day.
- There will be separate proceedings for determining damages and costs which will follow the first instance decision.
- The UPC has specific procedures to address certain aspects of patent litigation, including for instance:
  - Applications for provisional measures (including applications to obtain a preliminary injunction);
  - Order for inspections ("dawn raid" to collect facts and secure evidence).

# Timeline of First Instance Infringement Proceedings

INFRINGEMENT	REVOCATION COUNTERCLAIM	APPLICATION TO AMEND	TIME ALLOCATED		
Statement of claim	_	_	_		
Statement of defense	Counterclaim for revocation	_	3 months	CEDURE	
Reply	Defense to counterclaim	Application to amend	2 months	WRITTEN PROCEDURE	
Rejoinder	Reply	Defense	2 months		
_	Rejoinder	Reply	1 month		
_	_	Rejoinder	1 month		
Interim Proced (may include a	Up to 3 months	INTERIM			
Oral Hearing (to be complete	Within 1 month				
Decision (reasons may be provided subsequently)			May be on day of hearing	ORAL	

# Timeline of Procedure to Lay Open Books

Phase 1: Request to lay open books

REQUEST TO LAY OPEN BOOKS	TIME ALLOCATED	
File application	Within one year after decision on merits	WRITTEN PROCEDURE
Defense brief	2 months	PROC
Reply brief	14 days	HEN
Rejoinder	14 days	WRIT
Interim Procedure	Reduced timetable, max. 3 months	INTERIM
Oral Hearing	Reduced timetable, max. 1 month	AL
Decision on request to lay open books	Within 6 weeks	ORAL
Enforcement	Time set by the court. Periodic penalty payments if defendant fails to comply	

# Timeline of Procedure for Determination of Damages

Phase 2: Determination of Damages

APPLICATION FOR THE DETERMINATION OF DAMAGES	TIME ALLOCATED	
File application	When the procedure for laying open of books is complete	WRITTEN PROCEDURE
Defense brief	2 months	PRO
Reply brief	1 month	HEN
Rejoinder	1 month	WB
Interim Procedure	Reduced timetable, max. 3 months	INTERIM
Oral Hearing	Reduced timetable, max. 1 month	ORAL
Decision for the determination of damages	Within 6 weeks	OR

# Languages before the UPC

The UPC as an international Court can conduct proceedings in various official languages of the participating Member States. The UPC Agreement provides several options for choice of the language of the proceedings:

# 1. Language determined for Local/Regional Division

- Local Divisions will use the (or one of the) official language(s) of the Member State hosting this division.
- The Member States hosting a Regional Division may determine the official language(s) used before the Regional Chamber.
- Other languages may be used in addition or instead of the official language, if designated by the respective Member State(s) (e.g., allowing proceedings in English also).
- Most Member States have announced that they will accept English at their Local/Regional Divisions.

# 2. Language of the patent in dispute

- Before the Central Division, proceedings will be in the language of the patent in dispute (English, German or French).
- The language of the patent can also be used in the Local Divisions if the parties agree on this, or when the Court, after having heard the parties, decides accordingly.

# 3. Consequences of applicable language

- Irrespective of the language of the proceedings, upon request of the defendant, the patent in dispute has to be translated into the official language of the Member State where the defendant has its seat or where the infringement was committed.
- Every document will need to be translated into the language of the proceedings, unless the panel waives the translation requirement.
- Simultaneous interpretation of oral hearings is possible.
- The language of the proceedings will be an important factor in selecting where to bring infringement proceedings. In pan-European disputes, the plaintiff will have multiple options for choosing the language for the proceedings to be litigated.

# Jurisdiction and Forum Shopping

- Infringement proceedings can be brought before the Local or Regional Division where:
  - ° an act of infringement has occurred, or
  - where the defendant, or one of the defendants, has its residence or principal place of business.
- Infringement proceedings can also be brought before the Central Division if:
  - defendant does not have a residence or place of business within a UPC territory, or
  - o the Member State where infringement has occurred or in which the defendant has its residence or principle place of business has neither a Local nor a Regional Division.
- Actions for revocation or non-infringement shall be brought before the Central Division, or, when an infringement action is already pending, as a counterclaim in the pending infringement action before a Local/Regional Division. If an action for infringement is initiated within three months of the inception of an action for revocation or for non-infringement, the local or Regional Division can decide to proceed with both actions.
- Parties may agree to bring actions before the Division of their choice.

# Infringement and Validity: Bifurcation or Not

- The UPC allows either German-style bifurcation or joint hearing of infringement and validity.
- If a counterclaim for revocation is launched in an infringement action, the Local/Regional Division may:
  - proceed with both actions (infringement and revocation); or
  - 2. refer the counterclaim for revocation to the Central Division (i.e., bifurcation); or
  - 3. with the agreement of the parties, refer both actions to the Central Division.
- The various Local/Regional Divisions will likely develop their own practice on this, thus encouraging forum shopping.

# Opting Out and Opting Back In

- An EP or a pending EP application can be "opted out" of the jurisdiction of the UPC. This will avoid a central attack on validity or central actions for a declaration of non-infringement before the UPC. This is possible during the three-month "sunrise period" immediately preceding the entry into force of the UPC and up to one month before the end of the transitional period. Optout extends to any SPC based on the EP. Opt-out of a parent EP application does not extend to the divisional EP application. There is no possibility to opt out a UP.
- From a practical perspective, the proprietors of an EP or the applicants of an EP application request an opt-out through the UPC Registry using the UPC Case Management System. The opt-out becomes effective when it is entered into the UPC register. Where an EP has multiple proprietors/applicants, an opt-out must be made by them jointly. Licensees, even exclusive licensees, cannot apply for an opt-out. There will be the possibility to opt-out multiple EPs / EP applications in one single step.
- During the "sunrise period", EPs and pending EP applications can be opted out without any risk of an action being brought before the UPC. Opt-out is still possible during the transitional period so long as no action has been brought before the UPC prior to the opt-out being entered in the UPC register.
- Opt-outs are effective for all designated states of the EP. Once opted out, the UPC has no jurisdiction over the EP - only national courts will have jurisdiction over it. The EP will then remain outside the UPC for the lifetime of the patent, including after the transitional period. This also applies to any SPC based on the opted-out EP.
- An opted-out EP or EP application can be opted back
  in at any time by withdrawal of the opt-out with the
  Register, unless an action has been brought before a
  national court. A second opt-out after opting back in is
  not possible.
- Whether or not to opt out existing EPs or pending EP applications should be decided on a case-by-case basis. Proprietor/applicant/licensees should therefore consider and discuss opt-out strategy before the "sunrise period" starts.
- There are no fees for opt-out or a withdrawal of opt-out.

# Court Fees: Infringement Action (First Instance)

Proposed court fees for an **infringement action** at the UPC, compared to existing national proceedings:

VALUE OF ACTION (€)	UPC COURT FEES (€)	GERMANY COURT FEES (€)	UK COURT FEES* (€)	FRANCE COURT FEES (€)
100,000	11,000	3,378	5,977	0
500,000	11,000	11,703	11,954	0
1 million	15,000	17,643	11,954	0
2 million	24,000	29,523	11,954	0
5 million	43,000	65,163	11,954	0
10 million	76,000	124,653	11,954	0
30 million	161,000	362,163	11,954	0
50 million	261,000	362,163	11,954	0
100 million	336,000	362,163	11,954	0

<sup>\*</sup> Fees in the IPEC are subject to a different cost regimes.

# Court Fees: Revocation Action (First Instance)

Proposed Court fees for a **revocation** action at the UPC, compared to existing national proceedings:

VALUE OF ACTION (€)	UPC COURT FEES (€)	GERMANY COURT FEES (€)	UK COURT FEES (€)	FRANCE COURT FEES (€)
100,000	11,000-20,000*	5,081	680	0
500,000	11,000-20,000*	17,555	680	0
1 million	16,000-20,000*	26,465	680	0
2 million	20,000	44,285	680	0
5 million	20,000	97,745	680	0
10 million	20,000	186,845	680	0
30 million	20,000	543,245	680	0
50 million	20,000	543,245	680	0
100 million	20,000	543,245	680	0

<sup>\*</sup> Lower number refers to revocation action brought as a counterclaim to infringement proceedings.

# Recoverable Attorneys' Fees (First Instance)

Loser-Pays Principle: Proposed net recoverable **attorneys' fees** at the UPC, compared to existing national proceedings:

VALUE OF ACTION (€)	UPC (€, UP TO)	GERMANY (€, CA.)	UK	FRANCE
100,000	38,000	20,500	Usually 60-70% of actual attorneys' costs incurred. Not dependent on value of action.	Usually 30-70% of actual attorneys' costs incurred. Not dependent on value of action.
500,000	56,000	43,00		
1 million	112,000	67,000		
2 million	200,000	112,000		
5 million	600,000	240,000		
10 million	800,000	468,000		
30 million	1.2 million	1,200,000		
50 million	1.5 million	1,200,000		
100 million	2 million	1,200,000		

(Assuming representation by a litigator together with a patent attorney, without VAT and expenses, including a separate nullity action for Germany with an increase value of 25%.)

# **Truth, Justin**

**From:** Sorare, Laura

Sent: Monday 25 September 2017 11:15

To: Truth, Justin

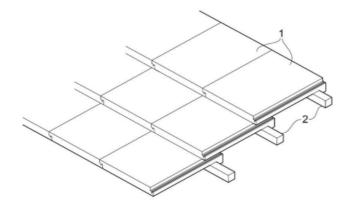
**Cc:** Montretou, Gaspard g.montretou@inventor.com

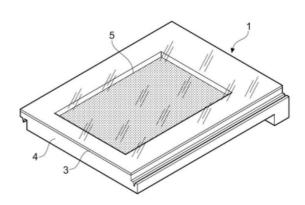
**Subject:** INVITATION: Meet us at Batomat 2017 to discover our new roof tiles!



Dear Customers,

We offer you the opportunity to discover our new photovoltaic roof tiles that are easy to use and install:





These innovative photovoltaic roof tiles have the advantage by their constitution and the choice of materials to be incredibly efficient to supply electricity (<u>very high transparency</u> of 91,5% of the glass of the cover of the solar collector). They are also able to heat a building or a house thanks to a flat fluid-tight passageway (connectors and tubes filled with <u>circulating</u> fluid located behind the solar collector).

We are proud to introduce you to this new technology at Batomat show on 14 October 2017. Famous Professor G. Montretou from the University of Marseille, France, will be happy to show you two different versions of this revolutionary photovoltaic roof tile in detail and explain its structure.

In case you cannot attend our presentation at Batomat, you can find our promotional video at the following URL: <a href="https://www.youtube.com/LNTaB2017">www.youtube.com/LNTaB2017</a>, where you will find the explanation of the functioning of the new photovoltaic roof tile.

We are looking forward to meet you at Batomat. Our commercial team remains available to answer any questions you may have.

Your sincerely,

La Nuova Tessera team



# Replace or delete your video

You can delete any video you uploaded to your YouTube channel. You can't replace a video since any new video uploads will get a new URL, but you can change the existing video.



Computer

Android

iPhone & iPad

# Delete your own videos

You can remove any videos that you uploaded from your own Google Account. If you delete a video, it's permanently deleted — you can't recover it through YouTube. If you'd like to watch the video in the future, make sure you have a backup saved.

- 1. Sign in to YouTube Studio
- 2. From the left menu, select **Content**.
- 3. Point to the video you'd like to delete and select More : > Delete forever | ...
- 4. Check the box to acknowledge that your video will be permanently deleted.
- 5. Select **DELETE FOREVER**.

When you choose to delete a video from your YouTube channel, we immediately start the removal process and it will no longer be searchable within YouTube. Data associated with the video such as Watch time will still be part of aggregate reports, but will not be attributed to the deleted video. Learn how to delete videos in bulk.

# Replace a video

You can't replace a video because any new video you upload to YouTube will get a new URL. Instead, you can change an existing video:

- Trim your video: On a computer, you can cut out the beginning, middle, or end of your video.
- Add cards to your video: You can use cards to add new elements to your video. Cards can show specific websites and more.
- Change your video's title and description: You can organize and change your video's title, category, description, and privacy settings.

To report abuse, harassment, inappropriate content, or privacy complaints, visit the Safety Center . For copyright concerns, visit the Copyright Center .