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European Biotech Patent Law Update

17 July 2018

Matthew Caines

Antony Latham

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 www.dyoung.com

Webinar agenda

- T 239/16 – clinical trials data
- T 1931/14 – interpretation of method claims

- T 282/12 – priority: the “first” application
- T 1833/14 – public prior use

T 239/16

- Novartis
- Zoledronic Acid (ZOMETA®)
- Approved in US and EU for treatment of multiple myeloma, prostate cancer, bone metastases, hypercalcemia of malignancy
- Bisphosphonates - Inhibit bone resorption
- ZOMETA® sales about $1.26 billion worldwide in 2012
- Basic patent expired 2013
- Second medical use – treatment of osteoporosis

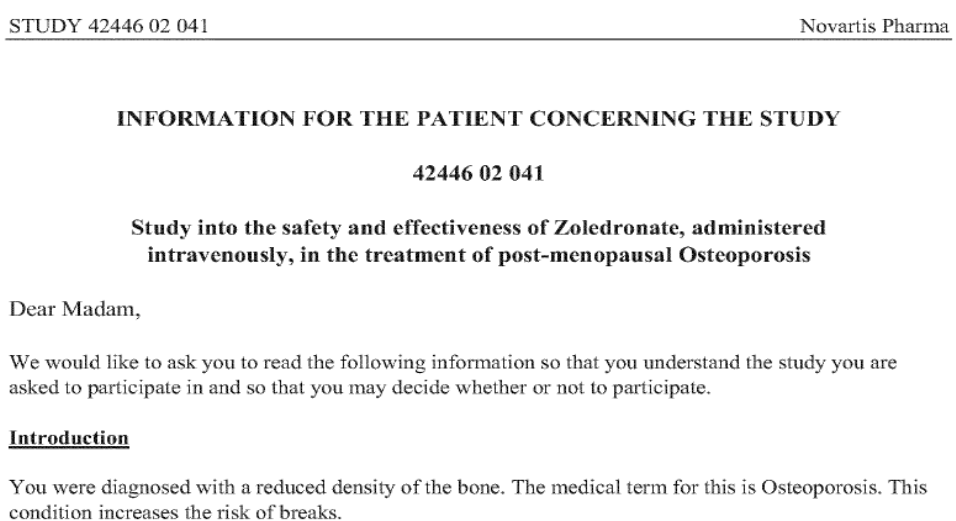
T 239/16

- EP 1 591 122 B (filing date: June 2001)
- Opposition:
  - Five opponents
  - Patent maintained in amended form (AR1)
- Appeal – claim 1:

> *"1. Zoledronic acid or a pharmaceutically acceptable salt thereof or any hydrate thereof for use in a method of treating osteoporosis in which the zoledronic acid or the pharmaceutically acceptable salt therefore or the hydrate thereof is administered intravenously and intermittently and in which the period between administrations is about one year."*

T 239/16 – Document (55)

- Decision based on disclosure of Document (55)
  - Clinical trial patient information leaflet
  - Discloses a once yearly intravenous administration of zoledronic acid (amongst other dosing regimens)



STUDY 42446 02 041 Novartis Pharma

INFORMATION FOR THE PATIENT CONCERNING THE STUDY

42446 02 041

Study into the safety and effectiveness of Zoledronate, administered intravenously, in the treatment of post-menopausal Osteoporosis

Dear Madam,

We would like to ask you to read the following information so that you understand the study you are asked to participate in and so that you may decide whether or not to participate.

Introduction

You were diagnosed with a reduced density of the bone. The medical term for this is Osteoporosis. This condition increases the risk of breaks.

T 239/16 – Public availability

- Was document (55) made available to the public?
  - **YES**
  - No “special relationship”
  - No explicit or implied obligation of confidentiality
  - Affidavit from a Professor supervising the trial:

> 6 I explained the contents of the Standard Consent Form annexed at LV-1 with my patients. I told my patients that before signing the form they should openly discuss the treatment referred to in the Standard Consent Form with anyone, including their family and family doctor. Indeed, I encouraged my patients to do so. That is, without any obligation of confidentiality.

  - “anyone”

T 239/16 – Novelty

- Is Document (55) novelty-destroying?
  - **NO**
  - Relates to treatment of post-menopausal osteoporosis in human females using a once-yearly i.v. dose
  - No explicit or implicit disclosure of effective treatment
  - Conclusion:

*"There remains **a certain residual doubt** that the effect, i.e. the treatment of post-menopausal osteoporosis in human females getting an intravenous dosage of 4 mg zoledronic acid once a year, is/will be achieved"*

T 239/16 – Inventive step

- Lack of inventive step in view of Document (55)?
  - **YES**
  - Technical problem: provision of an effective treatment of osteoporosis
  - Would the “certain residual doubt” diminish the skilled person’s expectation of success of once-yearly treatment?

T 239/16 – Inventive step

> The board considers that the mere fact that an active agent selected from the group of bisphosphonates is being tested in a clinical study for the treatment of osteoporosis (as disclosed in document (55)) leads to an expectation of success, due to the fact that clinical studies are based on data obtained by pre-clinical testing both in vitro and in animals and require authority approval which takes ethical considerations into account. This means in the present case that the skilled person would expect all study arms to treat osteoporosis effectively, unless he was dissuaded from this by the prior art

- No dissuasion in the prior art – no indication of expected failure
- **Lack of inventive step** – patent revoked

T 239/16 – Established case law

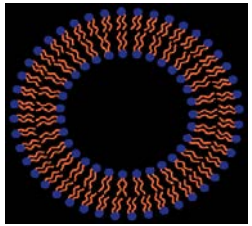
- **T 158/96** – Pfizer / sertraline
  - Treatment for OCD
  - Proprietor: the mere fact that a clinical study is performed does not as a rule mean that the particular therapeutic effect is achieved.
  - Board: T 158/96 relates to novelty not inventive step. For assessment of inventive step, certainty as to the outcome of a clinical trial is not required.
  - Further distinction: Emphasis on pre-clinical data for osteoporosis *versus* OCD, for which there was no animal model.

T 239/16 – Established case law

- **T 715/03** – Pfizer/ ziprasidone

  - Treatment for Tourette's syndrome – no pre-clinical model
  - Board: Zoledronic acid belongs to bisphosphonate class of drugs, which are established in the treatment of osteoporosis. Ziprasidone was remote from other chemical classes

T 239/16 – Established case law



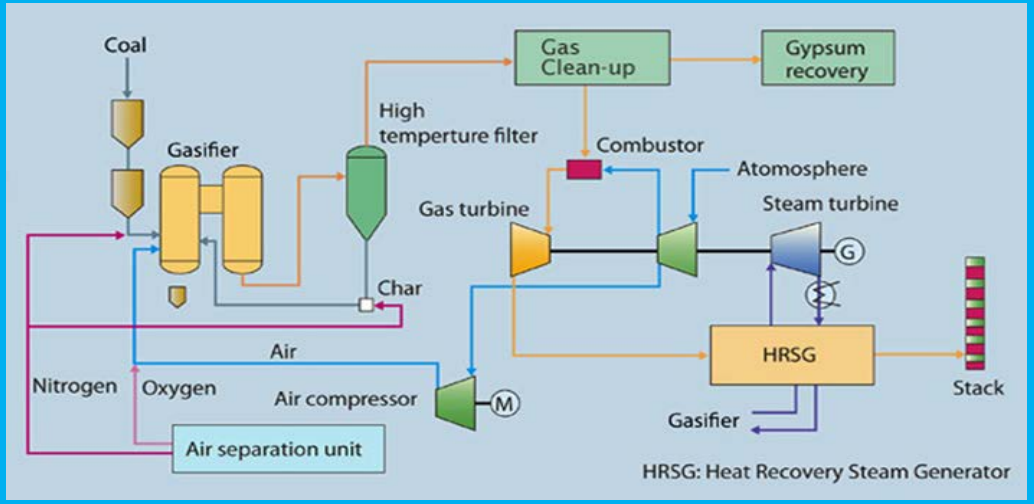
- **T 2506/12** – Pharma Mar / Doxorubicin-Ecteinescidin
  - Reasonable expectation of success seen in view of clinical data – different circumstances.
  - Board: *"Clinical trials in humans are planned scientific investigations. They require authority approval, which is only given after a risk/benefit evaluation. For ethical (but so economic) reasons it has to be ensured that research risks are minimised and are reasonable in relation to any potential benefits. Ethical and economical considerations require that the "benefit" will arise with reasonable certainty and will not only "be hoped for". This has to be taken into consideration as part of the technical circumstances when assessing the level of confidence of the skilled person in making rational predictions about achieving the envisaged treatment. Consequently, even though the circumstances are different from those of case T 2506/12, that does not automatically mean that an inventive step is to be acknowledged."*

T 239/16 – Lessons and practice points

- When to file?
  - Before or after (pre-)clinical trial?
  - Plausibility *versus* disclosure
- Factors to consider:
  - Rarity of disease / condition
  - Availability of pre-clinical models
  - Compound of a known class with similar MoA?
  - Confidentiality of clinical trials

T 1931/14

- Not a biotech / pharma case – important principles
- GE Energy
- Integrated gasification combined cycle (IGCC)
- Process for producing oxygen for input



T 1931/14

- EP 1 053 392 B
- Opposition filed
- Patent revoked – lack of novelty over a US patent (D6)
- Appeal - claim 1:

  “A process for producing oxygen…for fuelling an IGCC power generation system…comprising…”

T 1931/14 – Arguments of the parties

- Respondent / opponent
  - The feature “for fuelling an IGCC power generation system” is to be regarded as being merely “suitable for” such a purpose
  - D6 discloses a process for producing oxygen which is “suitable for” this purpose
- Appellant / proprietor
  - The feature “to fuel an IGCC power generation system” is to be regarded as a functional technical feature of the claim
  - D6 does not disclose such a feature

T 1931/14 – EPO Guidelines

- F-IV, 4.13:

"In contrast to an apparatus or product claim, in the case of a method claim that defines a working method which, for example, commences with such words as: "Method for remelting galvanic layers", the part "for remelting ..." should not be understood as meaning that the process is merely suitable for remelting galvanic layers, but rather as a ***functional feature*** *concerning the remelting of galvanic layers and, hence, defining one of the method steps of the claimed working method (see T 848/93).*

A claim which is directed to a method or ***process aiming at a certain purpose for the production of a product ("method of manufacture")*** *has to be understood in the sense that the method or process has to be merely* ***suitable for*** *the production of the product, rather than comprising the use as an integral method step. Consequently, a prior disclosure of the same method, which is suitable for producing said specific product but does not indicate that the specific product is produced with it, anticipates a claim to the method for the production of that specific product."*

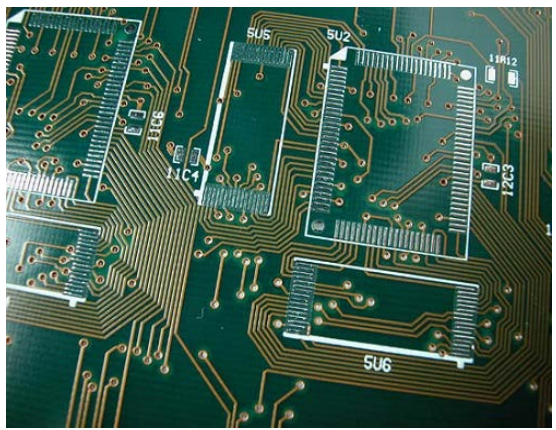
- Emphasis on "production of a product"

T 1931/14 – Established case law

- **T 848/93** *versus* **T 304/08**
- Respondent: *“There may be an occasion for referral to the Enlarged Board of Appeal”*
- Board: no conflict

T 1931/14 – Established case law

- **T 848/93 –** Siemens
  - *“Method for remelting galvanic layers on circuit boards”*
  - Claim requires that the method actually be carried out by melting a galvanic layer on a circuit board.
  - Claimed purpose defines a specific application or use of the method, and as such represents a limitation of the method.



T 1931/14 – Established case law

- **T 304/08 –** BASF
  - *“Method for reducing malodor in absorbent products”*
  - Purpose defined in terms of intended technical effect.
  - Whilst this would represent a limiting feature for the *use* of a substance, the same cannot be said for a method for producing a product.
  - Interpreted as “suitable for” (reducing malodour)

T 1931/14 - Decision

*"The two decisions demonstrate that in the context of a method it is important to differentiate between different types of stated purpose, namely those that define the **application or use of a method**, and those that define **an effect arising from the steps of the method** and implicit therein.*

Where the stated purpose defines the specific application of the method, in fact it requires certain additional steps which are not implied by or inherent in the other remaining steps defined in the claim, and without which the claimed process would not achieve the stated purpose (e.g. no actual re-melting of a galvanic layer would occur). In this manner the stated application represents a genuine technical limitation of the method and the claimed method must be applied in that manner.

On the other hand, where the purpose merely states a technical effect which inevitably arises when carrying out the other remaining steps of the claimed method (e.g. the malodor is inherently reduced) and is thus inherent in those steps, such a technical effect has no limiting effect because it is not suitable for distinguishing the claimed method from a known one."

T 1931/14 – Lessons and practice points

- Welcome clarification
- Relevance to biotech / pharma
  - *“Method for removing impurities…”*
  - *“Method for purifying (a product)…”*
- Carefully consider interpretation of method claims when drafting. Where possible:
  - Include both “limiting” and “non-limiting” method claims
  - Include fall-back positions which arguably make the claim “limited”
  - Include corresponding “use” claims

T 282/12

- Impact of partial priority in view of G 1/15 – what constitutes the “first application”

- Relevance to filing strategies

T 282/12

- EP1773302 – Rapidly disintegrating gelatinous coated tablets
- Filed 16 February 2005
- Claimed priority from D1 (US 10/898061) filed 23 July 2004

- Opposition – Patent maintained (grounds: novelty, inventive step and sufficiency)

T 282/12

- Appeal – Claim 1:

A dosage form comprising:

a) a core having an exterior surface and first and second ends;

b) a subcoating over portions of the exterior surface of the core;

c) a first gelatinous coating over at least part of the subcoating; and

d) a second gelatinous coating over at least part of the subcoating;

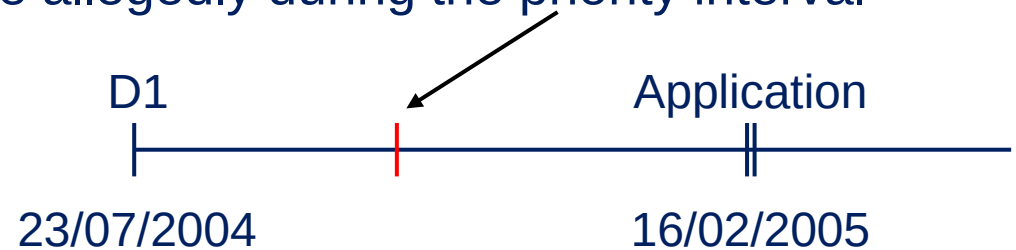
wherein the core is a compressed tablet; wherein the compressed tablet has an elongated shape; wherein the first and second gelatinous coatings are provided on said first and second ends of the core; wherein said first and second gelatinous coatings form a gap through which the subcoating is exposed, the gap being from 3% to 33% of the length of the elongated tablet as measured along its longest axis; and wherein at least one opening is provided through at least the subcoating to expose the exterior surface of the core.

T 282/12 – Novelty

- Prior art:
  - Public prior use of “Extra Strength Tylenol Rapid Release Gels”
  - Coated oral dosage form of acetaminophen
  - Two gelatinous coatings
  - Gap through which a subcoating is exposed – width approximately 17% of the length of the dosage form

T 282/12 – Novelty

- Prior art:
  - Public prior use allegedly during the priority interval



  - Necessary to assess the validity of the priority date

Priority

- Article 87(1) EPC:

  Any person who has duly filed,

  […]

  an application for a patent, a utility model or a utility certificate, or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application.

T 282/12 – Priority

- Same invention:
  - “shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority”

  - Not disputed by the parties

T 282/12 – Priority

- First application:
  - “right of priority during a period of twelve months from the date of filing of the first application”
- Opponent alleged that an earlier filing (D22), not D1, should be regarded as the “first application”

T 282/12 – Priority

- D22 cf. D1:
  - Proprietor argued that Patent and D1 differ from D22 in the gap between the two gelatinous coatings:
    - D1: 3% to 33%
    - D22: 5% to 33%
  - Not disputed that D22 discloses all other features of Main Request and of D1

OD’s decision (December 2011)

- G 2/98
- Strict approach to “same invention” – added matter test:

> “The requirement for claiming priority of the “same invention”, referred to in Article 87(1) EPC, means that priority of a previous application in respect of a claim in a European patent application in accordance with Article 88 EPC is to be acknowledged only if the skilled person can derive the subject-matter of the claim directly and unambiguously, using common general knowledge, from the previous application as a whole.”

OD’s decision (December 2011)

- OD held that D1 is the “first application”:
  - Added subject matter test
  - Gap width of 3% to 33% (D1) represented added subject matter compared to the gap width of 5% to 33% recited in D22
  - D22 is not the “first application”
  - Main Request benefits from priority date of D1
  - Public use of Tylenol does not constitute prior art
- Opponent appealed

Partial priority

- Article 88 EPC:

> (2) Multiple priorities may be claimed in respect of a European patent application, notwithstanding the fact that they originated in different countries. Where appropriate, multiple priorities may be claimed for any one claim. Where multiple priorities are claimed, time limits which run from the date of priority shall run from the earliest date of priority.

Partial priority – G 1/15

"Under the EPC, entitlement to partial priority may not be refused for a claim encompassing alternative subject-matter by virtue of one or more generic expressions or otherwise (generic "OR"-claim) provided that said alternative subject-matter has been disclosed for the first time, directly, or at least implicitly, unambiguously and in an enabling manner in the priority document. No other substantive conditions or limitations apply in this respect."

G 1/15

1. Identify subject matter directly and unambiguously disclosed in the priority document.

6.4 In assessing whether a subject-matter within a generic "OR" claim may enjoy partial priority, the first step is to determine the subject-matter disclosed in the priority document that is relevant, i.e. relevant in respect of prior art disclosed in the priority interval. This is to be done in accordance with the disclosure test laid down in the conclusion of G 2/98 and on the basis of explanations put forward by the applicant or patent proprietor to support his claim to priority, in order to show what the skilled person would have been able to derive from the priority document. The next step is to examine whether this subject-matter is encompassed by the claim of the application or patent claiming said priority. If the answer is yes, the claim is de facto conceptually divided into two parts, the first corresponding to the invention disclosed directly and unambiguously in the priority document, the second being the remaining part of the subsequent generic "OR"-claim not enjoying this priority but itself giving rise to a right to priority, as laid down in Article 88(3) EPC.

G 1/15

1. Identify subject matter directly and unambiguously disclosed in the priority document.
2. Is this subject matter encompassed by the claim?

6.4 In assessing whether a subject-matter within a generic "OR" claim may enjoy partial priority, the first step is to determine the subject-matter disclosed in the priority document that is relevant, i.e. relevant in respect of prior art disclosed in the priority interval. This is to be done in accordance with the disclosure test laid down in the conclusion of G 2/98 and on the basis of explanations put forward by the applicant or patent proprietor to support his claim to priority, in order to show what the skilled person would have been able to derive from the priority document. The next step is to examine whether this subject-matter is encompassed by the claim of the application or patent claiming said priority. If the answer is yes, the claim is de facto conceptually divided into two parts, the first corresponding to the invention disclosed directly and unambiguously in the priority document, the second being the remaining part of the subsequent generic "OR"-claim not enjoying this priority but itself giving rise to a right to priority, as laid down in Article 88(3) EPC.

G 1/15

1. Identify subject matter directly and unambiguously disclosed in the priority document.
2. Is this subject matter encompassed by the claim?
3. If yes, conceptually divide the claim.

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T 282/12 – Decision

- Comparing D1 and D22 – quoting G 2/98:

  “in order to avoid any inconsistency, the criteria to be applied in assessing (i) whether an application is to be regarded as the first application for the purposes of determining priority and (ii) whether a claim in a later European patent application is in respect of the same invention as the priority application pursuant to Article 87(1) EPC must be the same”

T 282/12 – Decision

- Comparing D1 and D22:
  - 3% to 33% range of D1 is not the same as the 5% to 33% range of D22
- However, G 1/15 acknowledges the concept of partial priority:

> "In the Board's view, for reasons of consistency, the rationale of decision G 1/15 (concept of partial priority) must also apply in the context of deciding whether an application from which priority is claimed is the first application within the meaning of Article 87(1) EPC."

T 282/12 – Decision

"Indeed, just as a priority application and a patent claiming priority therefrom may partially relate to the same invention, the priority application and an earlier application filed by the same applicant may also partially relate to the same invention. In that case, the priority application would be the first application in respect of only that part of the invention which is not the same as in the earlier application"

T 282/12 – Decision

1. Identify subject matter directly and unambiguously disclosed in the priority document.
2. Is this subject matter encompassed by the claim?
3. If yes, conceptually divide the claim.

"D22 discloses the range 5% to 33% for the gap width"

T 282/12 – Decision

1. Identify subject matter directly and unambiguously disclosed in the priority document.
2. Is this subject matter encompassed by the claim?
3. If yes, conceptually divide the claim.

"The range of D22 is encompassed in the range of D1 (3% to 33%)"

"The invention of D1 is conceptually divided into two parts, one of them being the same invention as D22 (range 5% to 33%)"

T 282/12 – Decision

"Thus, in respect of the sub-range 5% to 33% D1 is not the first application within the meaning of Article 87(1) EPC. It follows that the part of claim 1 of the main request concerning the dosage forms wherein the gap width is between 5% to 33% of the length of the dosage form is not entitled to the priority date of D1.

This part of claim 1 of the main request is the relevant one in relation to the alleged prior use since, according to the appellant, the gap between the two gelatinous coatings of the product "Extra Strength Tylenol Rapid Release Gels" is around 17% of the length of the tablet."

T 282/12 – Decision

- Case remitted to OD to consider novelty in view of alleged public prior use

T 282/12 – Decision

- Board agreed that:

  “broadening the invention disclosed in D22 by the filing of D1 did not give rise to a right of priority for the subject-matter already disclosed in D22 because this would result in an extension of the priority right by merely shifting the end point of a range”

T 282/12 – Decision

"an applicant could postpone the priority date of an invention disclosed in a first application, merely by filing a new application in which some alternative subject-matter has been added and this could be repeated several times. Under this assumption, even a cosmetic modification of the first invention could give rise to a new priority date, which would not be justified"

Summary

- Concept of partial priority applies to the assessment of the “first application”
- Effect on filing strategy should be considered
- Adjustment of subject matter in later filings might not give rise to a valid priority claim if partial priority applies

T 1833/14

- EP2243803
- Appeal – Claim 1:

  Heterophasic polypropylene composition comprising

  73 to 98 wt.-% of a polypropylene matrix (M) and

  2 to 27 wt.-% an elastomeric copolymer (E) being dispersed in the matrix (M), based on the polypropylene matrix (M) and the elastomeric copolymer (E),

  wherein the elastomeric copolymer (E) comprises units derived from

  propylene and

  ethylene and/or C4 to C20 α-olefin,

  […]

T 1833/14

- Alleged public prior use: “Rigidex®P450xHP60”

T 1833/14

- Alleged public prior use: “Rigidex®P450xHP60”
- Decision:

> “passages of G 1/92 also imply that a product put on the market is considered not to have been made available to the public within the meaning of Article 54(2) EPC if the skilled person had no means of establishing the composition or the internal structure of the product or was not able to reproduce it, in spite of the product being publicly available before the priority/filing date of the patent”

T 1833/14

- Mere disposal not sufficient
- Catalyst system, reacting system and process conditions are all of importance – not publically available

- Opponent argued it would not be reasonable that a publically available product falling under claim 1 could not anticipate the claim
- Application of the conditions of G 1/92 give rise to this conclusion – prior use must be an enabling disclosure

Questions…

We will email links to a recording and slides from today's webinar later this week.

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