Mock Certification Exam for
Patent Information Professionals 2011

PATENT INFORMATION ANALYSIS CERTIFICATION

MOCK EXAMINATION

Sample Answers

Paper B (Patent Analysis)
Chemistry

Please note: it is to be understood that the sample answers provided in this document are intended to serve as a guide and by no means represent definitive answers. It is entirely possible that additional answers not specifically disclosed in this document could be considered as satisfactory answers

Part 1: Short Questions and Sample Answers

1. Are the following priority claims valid?

   a. A Brazilian patent application filed 22 April 2010, claiming priority from a US application filed 22 April 2009?

   According to Article 4 C of the Paris Convention, priority can be claimed within 1 year, therefore this is a permissible priority claim.

   b. A German patent application filed 8 April 2010, claiming priority from a German utility model application filed 8 September 2009?

   Priority claims between patents and utility models are possible according to Paris Convention. The time elapsed is less than 1 year, therefore this is a permissible priority claim.

   c. A PCT application filed 17 May 2010, claiming priority from a PCT application filed 17 January 2010?

   An application may also claim priority from an application filed for the same territories. As the priority claim has been made within 1 year, this is a permissible priority claim.

Comments:

This question tests the knowledge of the candidate on the priority system (according to the Paris Convention). A patent information professional should be able to understand priority claim(s) as the priority date(s) affect whether a source of information is prior art.

2. Describe six differences between a utility model and a patent?

Possible responses include:

A utility model cannot be obtained in some jurisdictions/countries; whereas a patent can be obtained in such jurisdictions/countries.

The subject matter claimed in a utility model can be restricted to certain application areas or technical fields (e.g. a utility model in China cannot be granted for a process).

The duration during which a utility model protects a claimed invention is shorter than that of a patent, and varies from country to country. Usually the protection period is between 7 and 10 years, without the possibility of extension or renewal.

Depending on jurisdiction, only a set number of claims may be permitted for a utility model.

Utility models are generally less expensive to obtain and to maintain.

Examination of utility models often less stringent; e.g. only needing to satisfy a novelty standard (and possibly only a local novelty standard) is required. In many jurisdictions, patent applications are subject to substantive examination in which the patent claims must satisfy a novelty, inventive step (non-obviousness) and industrial utility requirements among other requirements.

A utility model can be published within a few months of filing; whereas a patent application, in most jurisdictions, is only published after 18 months from filing.

It takes a shorter period of time for a utility model to be granted than a patent. The registration process is often significantly simpler and faster, taking, on average, six months.

Publication kind codes for a utility model are different than the publication kind codes for a patent publication.

Protection for utility models is often sought for innovations of incremental character which may not meet the patentability criteria.

Comments:

A patent information professional should be aware of utility models and the unique characteristics when compared to patent applications. For example, if a patent information professional is conducting a novelty search or a patent infringement search s/he should take into consideration that utility models can be potentially relevant documents.

3. An EP-patent with a filing date of February 2000 is claiming priority from a Canadian patent application filed in April 1999. Which date should be considered when reviewing the results of an invalidation search and why? Please assume that grace period provisions available in Europe do not apply.

   - *If the priority date is valid for one or more claims then the relevant date is April 1999 for those claims.*
   - *If the priority date is not valid for one or more claims then the relevant date is February 2000 for those claims.*
   - *Potentially relevant EP patent applications that were published after February 2000, but that validly claim a priority date earlier than April 1999 could also be cited.*

Comments:

This question relates to the knowledge that the patent information specialist should have in his/her day-to-day work: thorough knowledge of the decisive date for novelty purposes.

4. In a family of patents the following family members are found. What is the expiry date of each of these members of this family, assuming that all necessary (annuity) fees have been or will be paid?

a. A US patent (US-A) filed 12 April 1994 and granted 16 March 1998;

The US application was filed before 8 June 1995, i.e. before the US patent term was changed to 20 years from filing date. Therefore the patent term is 17 years from the grant date and the estimated expiry date is 16 March 2015.

b. A Continuation-in-Part from US-A filed 12 January 1998 (US-B) and granted 2 August 2003;

This US application was filed after 8 June 1995. Therefore the patent term is 20 years from the earliest filing date in line, which is the filing date of US-A. The estimated expiry date is 12 April 2014.

c. A European patent (EP-C) filed 10 April 1995, claiming priority from US-A, granted 17 May 1999;

The patent term of EP patents expires 20 years after the filing date. The expiry date is therefore 10 April 2015.

d. A European divisional patent (EP-D) divided out from EP-C, filed 30 December 1998, granted 2 November 2002;

An EP divisional gets same filing date as the parent and the patent term is 20 years from the filing date. The expiry date is thus 10 April 2015.

e. A PCT-application (WO-E) filed 30 December 1998, claiming priority from US-B;

A PCT application has no 'expiry date'. The latest possible day to file national/regional applications is 30/31 months after priority. The priority claim has no effect on patent duration. Priority will only be valid for any new matter that has been added in US-B over US-A.

f.A Japanese patent (JP-F), which is the national phase of the PCT application noted in e) above, filed with the JPO on 10 July 2000 and granted on 7 October 2004.

National filings receive filing date of PCT-application. The patent term for Japanese patents is 20 years. Hence, the expiry date will be 30 December 2018.

Comments:

This question tests the knowledge of the candidate on patent terms (and expiry dates) over various jurisdictions.

5. As a result of the increasing importance of China in the field of Chemistry, you are often asked to assess the content and legal status of Chinese patent documents during FTO analysis. Assuming that you do not speak Chinese, how might you go about this? If the filing date of a Chinese application of potential relevance was 29 March 2008 and it has not yet been granted would you still cite the document for FTO if performing the analysis today?

- *Use Inpadoc (or similar, e.g. FAMPAT on Questel) to look for another family member which can be understood for analysis of claims.*
- *(If there are no other family members) find an English abstract from EPO or ChemAbs or DerwentWorld Patent Index or similar or obtain a machine translation.*
- *Check the CN legal status in Inpadoc and the China Intellectual Property Net (CNIPR) legal status in English service.*
- *For up-to-date legal status contact the Chinese Patent Office/Chinese Patent Attorney directly, as there is always delay for the legal status in English information reaching Inpadoc or CNIPR.*

- *CN patent applications must be requested to be examined within 3 years from filing (possibly extended for a further 2 months) otherwise they are deemed withdrawn. But, even if exam had not been requested within the prescribed time, it is still possible to restore the lapsed Chinese application.*

- *Candidate must state s/he would cite the document for FTO.*

Comments:

Patent information professionals can be called upon to conduct freedom to operate searched in countries other than their residence. Therefore, s/he has to have working knowledge of the patent life cycle in major patenting jurisdictions.

6. The expiry of a patent will normally be twenty years after the filing date. Name two situations in which the patent expiry date can be extended.

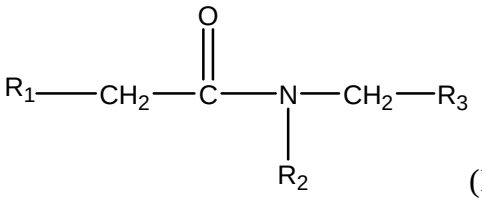
- *SPCs or other extensions for pharmaceutical/agrochemical patents that cover marketed products for which the extension is a compensation for lost patent time because of compulsory registration procedures.*

- *US-patent term extensions for making up lost patent time from delays caused by the USPTO.*

Comments

Patent information professional tasked with patent infringement searches need to understand how to apply date limitations to such searches taking into account the possibility of patent term extensions.

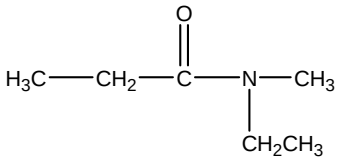
7. A prior art document discloses compounds of formula (I):



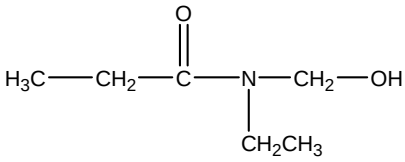
(I)

in which
R_1 is selected from the group of H, OH, lower alkyl;
R_2 is lower alkyl;
R_3 is selected from the group of H, OH, lower alkyl, phenyl.

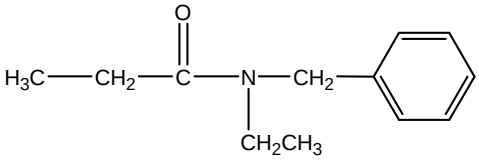
Only the following compounds are exemplified:



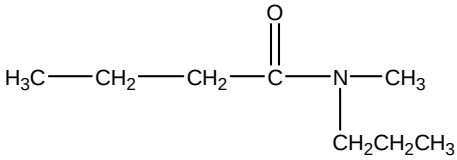
Example 1



Example 2



Example 3

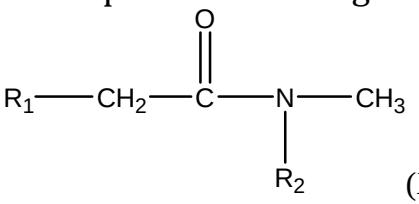


Example 4

wherein said compositions are claimed for alleviating chronic pain in cancer patients.

Is the prior art relevant, from a novelty perspective, to the following claims:

1. A compound according to Markush formula (X)



(X)

wherein
R_1 is selected from the group of H, OH, NH_2 or loweralkyl;
R_2 is lower alkyl.

RELEVANT. The prior art is relevant as Example 1& 4 falls within this Markush definition.)

2. A compound according to claim 1, wherein said compound is NH_2-CH_2-C(=O)-N(-CH_2-CH_3)-CH_3

NOT RELEVANT. The prior art is not relevant as it does not disclose this compound.

3. A compound according to claim 1, wherein said compound is CH_3-CH_2-CH_2-C(=O)-N(-CH_2-CH_2-CH_3)-CH_2Ph

NOT RELEVANT. Although this compound falls within the scope of formula (I) of the prior art, this compound is not specifically exemplified. Therefore, the prior art is not relevant as it does not specifically disclose this compound.

4. A compound according to claim 1, 2 or 3 for use in therapy.

RELEVANT (when claim 4 depends from claim 1) As the prior art already discloses a therapeutic use for the compounds claimed in claim 1, the prior art is relevant when claim 4 depends from claim 1.

NOT RELEVANT (when claim 4 depends from claims 2 or 3) the prior art does not disclose the compound claimed in claims 2 or 3 and therefore the prior art would not be relevant to the novelty of claim 4 when it depends from claims 2 or 3.

5. A compound according to claim 1, 2 or 3 for use in treatment of Alzheimer's disease.

   NOT RELEVANT as the prior art document does not disclose the use of the compounds claimed in claims 1, 2 or 3 for the treatment of Alzheimer's disease.

Comments:

This question tests the chemical knowledge and knowledge of how novelty is determined, especially novelty in selection inventions. Further knowledge is tested on patentability of medical treatment claims, both in Europe and USA.

8. List at least four different types of publications that could be cited as relevant in a novelty or patentability search?

Possible responses (this list is non-exhaustive):

books, journal publications, abstracts (of patents, journals or meetings), patent publications, dissertations, magazines, newspapers, (lecture) notes, leaflets, brochures, audio recordings, tv-recordings, movies, electronic publications (of any kind) such as PowerPoint presentations, blogs, discussion forums, Internet pages, etc. as long as these are publicly available.

Comments:

In general all the patent laws dictate that any disclosure in whatever form can be novelty destroying. Since the question only asks for 'publications', disclosures like 'on sale' and 'public prior use' are not appropriate answers.

9. Please describe how the 'grace period' functions under the differing jurisdictions of the European Patent Convention, US patent law (prior to the recently enacted America Invents Act: Leahy-Smith Amendments) and under Japanese patent law.

A grace period is an amount of time before the filing date of a patent application during which (some) publications, although publicly available, are disregarded when determining novelty or inventive step (obviousness).

- *Under the EPC there are only two occasions in which public disclosures do not count as prior art. These are discussed in Art. 55 EPC: publications by 'evident abuse' and disclosures at officially recognized exhibitions. In either case, the length of time between the disclosure and the filing date of the European patent application can only be up to 6 months.*

- *Under US law (prior to the recently enacted America Invents Act: Leahy-Smith Amendments), the grace period is defined as the period of one year before the filing date of the US patent application (in case such an application claims the benefit of an earlier US provisional application, one year before the priority date of said provisional) during which any third party or inventor derived disclosures (e.g. publications) anywhere in the world or public or secret use of the invention in the US or public or secret sales or offers of sale of the invention in the US are not deemed to be novelty destroying.*

- *In Japan a six-month grace period is provided for disclosures made through an experiment, publication, presentation at a study meeting or an exhibition (a trade fair or the World's Fair) or for if the invention becomes known to public against the applicant's will. Such disclosures do not form part of the prior art.*

Comments:

Patent information professionals need to understand that grace periods exist and as a result there is a potential for disregarding inventor-derived disclosures/activities when assessing novelty or inventive step (obviousness).

10. Which information in or on a patent document is of interest for a Freedom To Operate analysis and why? Is there any other kind of information, apart from that in or on the patent document itself, that is of interest?

- *One must look at the claims, because the claims define the monopoly granted or sought. Although in many jurisdictions, the claims are interpreted only in light of the application as filed, under US law, the file history of a US patent can be used to interpret the scope of the claims, so the file history is also important to consider when assessing US patent publications.*

- *Look at the front page to determine if the document is a published patent application or a granted patent (detectable by looking at the kind code or INID fields for example).*

- *Determine the legal status of the patent publication. If the document is a granted patent one would need to check if the patent could still be in force in that particular jurisdiction and if any post grant amendments have been made. If the document is a published patent application one would need to check if it could still be pending. Thus, in addition to considering the patent publication itself, it is important to obtain its current status (Pending? Under reexamination? Under opposition? Currently in force? Expired? Ceased?).*

- *Check for corresponding patent rights in other jurisdictions of interest. If a relevant document retrieved in a search is a published PCT patent application, for example, check to see if the 30/31month date has lapsed. If so, check to see if national or regional phase entry has occurred in the jurisdictions of interest. Similarly, in the case of a regional patent application, such as a European patent application,*

consider whether the jurisdictions of interest have been designated and if designation fees have been paid.

Comments: Patent information professionals conducting FTO searching need to understand that it is the claims that are relevant to patent infringement and that patent rights are territorial and can only be enforced if in force in the jurisdiction(s) of interest.

11. Which of the following documents may pose a potential patent infringement risk in Germany, assuming that the claimed subject matter in each of the listed documents is the same as the proposed product or process/method?

    a. A granted in force German patent
    b. A granted European patent with corresponding in force national patents in GB, FR, CH and DE
    c. A granted and in force German utility model
    d. A pending German patent application
    e. PCT application for which the earliest priority date claimed is 1 July 2009
    f. German registered and renewed trade mark
    g. a, b and c
    h. a, b, c, d, e
    i. any one of a-f

    H is the correct answer, as the question states a patent infringement analysis and not a FTO

Comments: option e) has been included to test whether a candidate identifies that a published PCT that was filed sometime after 1 July 2009 (which means that DE and all other states would have been designated) and for which national phase entry in DE is possible should therefore be included in the patent infringement analysis. The candidate needs to also understand priority claiming to understand that PCT claiming a priority date of 1 July 2009 as the earliest priority date would have had to have been filed within 12 months of that date in order to the earliest priority claim to have legal effect.

Certainly the patent infringmeent analysis can include PCT, European and German patents and patent applications and also the utility models. With respect to East-German patents, these could have been granted up to 1990 and would possibly be valid until 18 years after filing date (i.e. no longer after 2008). Thus, East-German patents no longer need to be included for this scenario.

With respect to trademarks, one can argue that FTO also depends on whether a product name/trademark may be used. As such, a trademark clearance could be incorporated in an FTO analysis. But, the question specifically asks about potential patent infringement risks.

12. Suppose that a European patent was granted; how could you determine whether the patent is still in force?

- *Depending on when the EP patent was recently granted, it may be possible that a post grant opposition has been filed. Need to check the EPO Register to determine if an opposition has been filed or if the opposition period has lapsed.*
- *Check to see if the EP patent has been validated in each designated state by checking the INPADOC/EPO Register, but often this source of information may not include current status information for each designated state*
- *Check national registers for status in each designated state; if status information is not available, then need to contact the Patent Office or a local patent attorney*
- *Check if annuity has been paid up to date for both the EP patent and each national patent for each designated state.*

13. What are the different "patent family" notions as you understand them. Give at least two definitions.

- *A simple patent family is one in which all patent family members share the same priority claim(s).*
- *An extended patent family is one in which patent family members can claim priority from different applications, but share at least one common priority claim. In an INPADOC patent family, it also possible to include documents that have the a similar scope of disclosure but that do not or may not directly claim priority from the common priority claim (e.g. non –Paris convention applications or CIP)*

Part 2 Sample Answers (novelty)

General Mark Deductions	Comments
	Marks should be deducted from the final score only once from total score for Part 2 if the candidate uses such phrases in his/her answer as 'one or more of D1-D5 is novelty destroying' OR that 'one or more claims of the Sonnepan application is not novel in light of ….' OR 'one or more claims is anticipated by the disclosure in…' OR 'one or more claims is not patentable'. Five marks will be deducted only once at the fist instance such a phrase has been used. The reason behind the deductions is that a patent attorney and not a patent searcher would render such conclusions and patent searchers should always refrain from drawing any conclusions about the novelty of an invention.

Prior Art Analysis (60 marks)	Comments
Remarks for D1	
	Marks awarded if candidate notes that the publication date of cited JP application (D1) is after both the filing and priority dates of the application in question. This tests the candidates knowledge of using filing dates for assessing novelty/validity of patents rather than using the publication date as for non-patent literature.
	Marks awarded for identifying that corresponding WO9952311, was **published** prior to the priority date of the Sonnepan application despite all the other corresponding family members, including D1 being published afterwards. The candidate should have stated that WO9952311 should be consulted (if published in English) as the machine translations of the claims for D1 are poor.
	Marks awarded for stating that D1 should be categorized as **relevant** and provide three possible reasons on the basis of technical disclosure of D1. The candidate should draw a comparison between the technical features of at least independent claim 1 of the Sonnepan application and the relevant technical features of D1 in providing his or her

Prior Art Analysis (60 marks)	Comments
Remarks for D1	
	answer.

Remarks for D2	
	Marks awarded if candidate states that the date of publication for this document needs to be further investigated **as the identified date cannot be assumed to be the date of publication**, but if 15 May 2000 is indeed the date on which the document was **made publicly available**, then state this assumption or alternatively state that perhaps P&G filed a patent application concerning the globules that pre-dates this announcement. However, no further mark can be awarded for commentary that is based on a hypothetical patent filing.
	Marks awarded for stating D2 should be categorized as **irrelevant** for the following reasons: Assuming the date of publication for D2 is 15 May 2000, then this document became publicly available after the date on which the priority application was filed (22 Dec. 1999), but before the date on which the SonnePan application was filed (19 Dec. 2000). The candidate should explain that the priority date of claims 1-5 and 7-11 is 22 Dec 1999, as the subject matter claimed in claims 1-5, 6 (in part) and 7-11 is disclosed by the priority document. Therefore, D2 does not appear to be a relevant document in respect of claims 1-5, 6 (in part) or 7-11. The priority date for claim 6 is also 22 Dec. 1999, with the exception of, when claim 6 is directed at probiotic microorganisms and/or prebiotic substances. Probiotic microorganisms and prebiotic substances were only disclosed as a possible biologically active substance at the date of filing of the Sonnepan patent application. D2 does

Remarks for D2	
	not disclose either probiotic microorganisms or prebiotic substances as a biologically active substance that can be included in the milk globules. Therefore, D2 does not appear to be relevant to the claimed food component of claim 6 when the biologically active substance is a probiotic microorganism and/or a prebiotic substance. The candidate should draw a comparison between <u>at least</u> independent claim 1 of the Sonnepan application and the disclosure of D2 in providing his or her answer. (Although the candidate may note that neither phosphatidylinositol nor phosphatidylcholine may fall within "enzymes, nutrients, natural or synthetic secondary plant constituents or substances having antioxidant activity " as claimed in claim 6, this a moot point and no marks should be awarded, as the priority date of claim 6 in respect of these classes of biologically active substances precludes D2 from being considered a relevant document.) (The candidate may also note that D2 does not disclose the subject matter of claims 7-11. But again, this is a moot point and no marks should be awarded, as the priority date of these claims precludes D2 from being considered a relevant document.)

Remarks for D3	
	Marks awarded if candidate states that US'414 published in 1996, a few years before the Sonnepan application or its corresponding priority application was filed.
	US'414 appears to be a relevant document on a novelty basis for the following reasons. US'414 discloses a nutritional product that contain: a) a guar gum core (**as the fibre**), b) a zein (protein) layer (**<u>as the biologically active material</u>**)-remember that the Sonnepan application is not limited to probiotic bacteria only, but rather the biologically

Remarks for D3	
	active substance is defined in the application as a substance that "can intervene in physiological processes" and US '414 states that the zein protein can lower cholesterol; and (c) a zein coating (**as the shell**). The Sonnepan application discloses that the shell forming substance can be a protein and also discloses that the biologically active substance can be a nutrient such as a protein. There is no disclosure in the Sonnepan application that the biologically active substance and the coating cannot be one and the same. It is apparent from US '414 that zein is a shell forming substance, as it is disclosed as an outer coating of the particle (see Encapsulation Experiments 2-4). The candidate should draw a comparison between <u>at least</u> independent claim 1 of the Sonnepan application and the disclosure of D3 in providing his or her answer. <u>Claim 1</u> Claim 1 of the Sonnepan application claims a *multifunctional* …structure (US'414 particles are multifunctional as they provide both guar gum as dietary fibre and cholesterol lowering agent and zein as cholesterol lowering agent.) Claim 1 of the Sonnepan application claims *a core comprising at least one dietary fibre, which core is surrounded by at least one biologically active substance* (US'414 particles are produced by spraying the zein protein on to the guar gum core see Encapsulation Experiments 2-4) Claim 1 of the Sonnepan application claims a *core and biologically active substance(s) are encapsulated by one or more shell forming substances* (US'414 particles are coated with zein see for Encapsulation experiment #2 where the fibre is first surrounded with zein, sieved and then coated once more with zein). Therefore, US '414 appears to be a relevant document in respect of claim 1.

Remarks for D4

	Awarded if candidate states that journal article published in 1996, a few years before the Sonnepan application or its corresponding priority application was filed.
	D4 does **not** appear to be a relevant document. Although D4 discloses microcapsules that contain alginate which is a plant fibre (as it is derived from brown algae) that is coated with chitosan or DEAE dextran (a shell forming substance that is a polysaccharide), the document does not disclose a microcapsule that contains a biologically active substance, as a pigment is encapsulated for the purpose of a synthetic aqueous based resin such as a latex. The candidate should draw a comparison between at least independent claim 1 of the Sonnepan application and the disclosure of D4 in providing his or her answer.

Remarks for D5	
	Although WO '501 was published on 24 December 2000, which was after the filing date of the Sonnepan patent application, the WO '501 claims an earlier priority date (7 June 1999) than the Sonnepan patent application (22 Dec. 1999). Thus, WO'501 may be citeable against the novelty of one or more claims of the Sonnepan patent application **if** (i) all of the subject matter in WO '501 was first disclosed in its priority document such that the priority date of WO '501 cannot be contested; (ii) both the WO'501 and the Sonnepan patent application are currently pending in one or more of the same jurisdictions; (iii) the patent law of the jurisdiction(s) include in the prior art base patent applications that are published after the filing date of the Sonnepan patent, but claim an earlier priority date; (iv) the priority date of WO'501 precedes the priority date of at least one of the claims of the Sonnepan patent application; and

Remarks for D5	
	(v)WO'501 discloses all of the features of one or more claims of the Sonnepan application.
	Assume that (i) -(v) are true The priority dates for claims 1-5, 6 (in part) and 7-11 is 22 Dec. 1999. When the food component claimed in claim 6 is a probiotic microroganisms and/or a prebiotic substance, the priority date is 19 Dec. 2000, because the priority document does not disclose probiotic microorganims or a prebiotic substance. As the priority date of WO'501 precedes both of these dates, the priority date of any of the claims will not be an issue. WO'501 appears to be a **relevant document** in respect of any one of claims 1-11 for the following technical reasons. WO'501 exemplifies particles that contain a) a psyllium core (**as the fibre**), b) a pectin or inulin layer (**as the biologically active material**-remember that the Sonnepan application is not limited to probiotic bacteria only, but rather the biologically active substance is defined in the application as a substance that "can intervene in physiological processes" and WO '501 states that the disclosed dietary fibres provide various gastrointestinal benefits including emptying time of the stomach; and (c) an inulin coating (**as the shell**). It is apparent from WO '501 that inulin is a shell forming substance, as it is disclosed as a outer coating of the particle that imparts a sweet taste. The candidate should draw a comparison between at least independent claim 1 of the Sonnepan application and the disclosure of D5 in providing his or her answer. Claim 1 Claim 1 of the Sonnepan application claims a *multifunctional* …structure (WO'501 particles are multifunctional as they

Remarks for D5	
	provide both pysllium as dietary fibre surrounded by pectin which is another dietary fibre. As dietary fibres are disclosed as having multiple functions, the particles could be considered multifunctional. Claim 1 of the Sonnepan application claims *a core comprising at least one dietary fibre, which core is surrounded by at least one biologically active substance* (WO '501 particles are produced by spraying the pectin on to the psyllium core see for example Test 1.) Claim 1 of the Sonnepan application claims a *core and biologically active substance(s) are encapsulated by one or more shell forming substances* (WO'501 particles are coated with inulin see for example Test 1). Therefore, WO'501 appears to be a relevant document in respect of claim 1.

Part 3 Sample Answers (patent infringement)

First of all, it should be considered that any remarks on the applicability of the documents because of the expiry dates should be awarded with an extra mark as shown in the marking guide. Also an explanation that for patent infringement/patent clearance searches both granted patents and patent applications may be considered relevant (as long as they are in force/pending), and that in the case of patent applications it is unknown whether the claims will be granted as published, should be awarded an extra mark as shown in the marking guide.

If a candidate only gives the correct relevancy of a document without discussion on what grounds, then only 1 mark per document will be awarded.

US 2008/233162 (Document 1)

This publication is a potentially relevant patent publication in the US, since it claims a scaffold as used in the client's production process (3-dimensional scaffold for tissue regeneration, comprising a polymer (such as PLA, PGA), formed by electrospinning. Potentially relevant claims are at least claims 1, 2, 5 and 14.

Candidate should mention that as the document is a patent application, it is unknown whether the claims will be granted as published.

US 5,192,312 (Document 2)

The filing date of this document is 5 March 1990, this will mean that the patent has expired on 9 March 2010. Assuming no patent term extension has been granted, it no longer provides any enforceable rights and for this reason, the patent does not appear relevant.

If the candidate does not assess the expiry of the patent, no marks will be awarded for any further discussion on the disclosure provided in US5192312 or the interpretation of its claims.

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US 5,855,610 (Document 3)

The candidate should mention that this patent claims a heart valve comprising a biodegradable polymer, seeded with presumably homologous cells and configured to form a tissue structure (such as a valve, see claim 3). The difference, however, is that claim 1 requires that the structure is formed by a.o. implanting the matrix into a recipient human and then harvesting the matrix, i.e. remove it from the patient again. This is certainly not performed in the process of the client.

However, claim 1 is a product claim (and for the relevant part a product-by-process claim), and the protection of such a claim would encompass all methods of forming it. Claim 1 thus should not be considered to be limited to the process of implanting and harvesting.

Furthermore, claim 6 is also potentially relevant, because it claims a heart valve, wherein the cells form extracellular matrix following implantation into a human. Although in the client's process, as described, the cells will have already formed some extracellular matrix before implantation, the process of forming matrix will continue after implantation. Thus claim 6 could potentially be relevant. One mark should also be awarded for stating that the document is potentially relevant.

Candidate should mention that the patent term has yet to expire

EP 1 077 072 (Document 4)

The process claimed in claim 1 of the patent is identical to the process of the client except for the conditions of the flow rate and pressure in the bioreactor. Whereas the claim is limited to a continuous or discontinuous increasing of flow rate and pressure, the client's process is described as a steady state process. Thus, claim 1 and its dependent claims should be considered irrelevant. However, the argument that the client's process also has a step in which the flow rate and pressure are increased (starting from 0 to reach a steady state). If this argument is not made and claim 1 is still

considered to be potentially relevant by the candidate, no marks should be awarded.

The potentially relevant claim of this document is independent claim 24. This claims a heart valve that can be produced by a method according to claim 1. From the description provided, it is possible that the heart valve produced by the client is a heart valve that can be produced by the method of claim 1. Thus, the document should be considered potentially relevant on the basis of claim 24.

Candidate should mention that the patent term has yet to expire

US 6,514,515 (Document 5)

This patent claims a biodegradable scaffold comprising poly(OH)alkanoate (which is meant for tissue engineering, especially for heart valves, see claims 27, 28 and 32). Such a scaffold is used in the client's process as described. Accordingly, the document should be considered potentially relevant provided that the client's scaffold has one or more of the claimed mechanical properties.

Candidate should mention that the patent term has yet to expire

Literature extract (Document 6)

Since this is a literature article and not a patent document, the article does not give rise to any enforceable rights. The document cannot pose a potential patent infringement risk and is therefore not relevant.

EP 1 339 356 (Document 7)

The difference between the product claimed in this patent and the client's product as described is that the scaffold of EP1339356 is seeded with (endothelial and) collagen cells. The candidates should note that the description of the client's process is silent on application of collagen cells, which of course does not mean that these cells will not be used and/or comprised in the product of the client. Thus, this document should be considered potentially relevant.

Candidate should mention that the patent term has yet to expire

WO 2006/099334 (Document 8)

The process and product described in the claims of WO2006/099334 differs from the process/products of the client, because the order in which the muscle cells (fibroblasts) and the endothelial cells are deposited on the scaffold is reversed. Thus, the document is not potentially relevant if the same claims as the PCT are granted at national or regional phase. Alternatively, the one mark may also be awarded if the candidate states that as the full description of WO2006/099334 had not been provided, it is possible that the reverse order had been disclosed but not claimed in the published PCT application. It is therefore possible that at national or regional phase of this international application, that granted claims in which the same order of cell deposition is claimed can arise, in which case the document could be potentially relevant.

EP 1 878 451 (Document 9)

This document is a family member of (the potentially relevant document) US 6,514,515. However, the device claimed in this document is only mentioned as a meniscus repair ad regeneration device, an articular cartilage repair device, a tendon repair device, a ligament repair device or a bone graft scaffold. Thus, the document does not appear to be potentially relevant.