Model Solution and Compendium-type Report for Paper DII

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Key Issues

It is important to realise that Oersted has no right to claim priority from DK1 because he was not the applicant for that application and is not successor in title. In addition, it is not possible for Skou, as sole applicant, to include in his proposed EP2 Oersted's inventions from EP3 without Oersted's co-operation.

To keep EP3 in force, a translation into English, French or German must be filed, while the fees due on filing must be paid together with the fee for further processing.

If Oersted is co-operative, it is not necessary to keep EP3 alive as long as it is sufficient to serve as a basis for a valid claim to priority, for example for filing an International application.

One of the problems to be resolved is that Oersted is the applicant for EP3, but the application includes inventions belonging either to Oersted or to Skou. One way of overcoming this problem is to file an International application with Skou and Oersted as co-applicants.

Candidates should indicate the subject-matter to be claimed when filing a new application, including the correct wording in the case of first and second medical claims. In this respect, based on the contracts and his own work Skou owns X, A, B, and both uses of X, while Oersted owns C, D, Y, and use of Z because these inventions were made by him and were not within the framework of the contracts.

The situation is different if Oersted is unco-operative. Entitlement proceedings should be started in Denmark. However, publication of EP3 will not take place for some time, if at all, and proceedings before the EPO cannot be stayed until after publication. An interim solution is to seek an injunction at national level requiring Oersted to maintain EP3 pending until the entitlement proceedings are resolved. The options for Skou following resolution of the entitlement proceedings should be explained bearing in mind that both parties own part of the overall subject-matter. However, it is unlikely a decision on entitlement will be available before the end of the priority year for DK1 (2 June 2021) so alternative options need to be explained, including securing cover for the newly-discovered anti-viral properties of X.

It should be appreciated that, although IN-DG is only a national application at this stage, it could give rise to an application in Europe and/or USA claiming priority from IN-DG. IN-DG gives rise to the earliest date for X and will pre-date any application based on DK1. Not only will the IN-DG derivative in Europe be novelty-only prior art for X and its first medical use, but any resulting patent would prevent Skou making and selling X unless he can negotiate a licence.

Timeline

Others		Client (SKOU)	
			Intention to file **PCT2** ○ also antiviral effect of X
EP3 offered to Elrond Pharma			
		02.03.2021	**TODAY**
EP3 filed (Oersted) Inventor: Oersted Priority from DK1 ○ Process C (50% higher yield) ○ Product X is formed together with Product Z as part of a Mixture Y ○ Product Z (also antihypertensive effect)	14.01.2021		
		Dec 2020	**Process B** (Skou & Oersted)
		02.06.2020	**DK1** filed (Skou) Inventors Skou & Oersted ○ Product X ○ Product X as a medicament ○ Pharmaceutical composition comprising product X ○ Product X as antihypertensive agent ○ Process A
IN-DG ○ Product X ○ Process P ○ In description: use as a medicine ○ In description: effect on cholesterol	15.04.2020		
		02.03.2020	priority year
Danish journal ○ Product Z ○ Use of Z as a catalyst in rubber vulcanisation process	2019		

Question A – What is the situation as regards DK1, EP3 and IN-DG

(i) Situation with DK1

DK1 is a pending patent application in Denmark and was filed in Danish on 2 June 2020 in the name of Skou (the client) and naming Skou and Oersted as inventors. There are no outstanding formalities and documents are in place clearly establishing Skou as being entitled to sole ownership. There is no claim to priority so the effective date of all the subject-matter of DK1 is 2 June 2020 and it is possible to file applications claiming priority from DK1 up to 2 June 2021. It is likely DK1 will be published around 2 December 2021.

DK1 claims:

c1) Product X,
c2) Product X for use as a medicament,
c3) Pharmaceutical composition comprising Product X,
c4) Product X for use as an antihypertensive agent, and
c5) Process A (however, Process A is not ideal).

IN-DG is an unpublished application having a filing date of 15 April 2020, which is earlier than DK1, and if IN-DG gives rise to an application effective in Denmarks or Europe (and designating DK) and claiming priority from IN-DG then it will constitute novelty-only prior art and would destroy novelty of c1) and c2) on publication.
However, c3), c4) and c5) would be novel.

(ii) Situation with EP3

EP3 was filed in Danish on 14 January 2021 naming Oersted as applicant and inventor. Because the application was filed in Danish, a translation into an official language (English, French or German – Art 14(2) EPC) is due within 2 months of the date of filing (Rule 6(1) EPC), i.e. by:

14.01.2021 + 2 months (Rule 131(4) EPC) → 14.03.2021 (Sunday) → 15.03.2021 (Monday – Rule 134(1) EPC)

This is still possible.

No fees were paid. EP3 claims priority from DK1, but the claim to priority is not valid because Oersted had no right to claim priority from DK1 (in the name of Skou) at the time EP3 was filed (Art 87(1) EPC). This cannot be corrected. No fees have been paid at this time (2 March 2021). The filing and search fees could be paid within 1 month of filing (Art 78(2) and Rule 38(1) EPC), i.e. up to:

14.01.2021 + 1 month (Rule 131(4) EPC → 14.02.2021 (Sunday) → 15.02.2021 (Monday – Rule 134(1) EPC)

This date has passed and EP3 is currently deemed withdrawn (Art 78(2) EPC).

EP3 describes Product X, its use as a medicament, a pharmaceutical composition comprising X, X for use as an antihypertensive agent, Mixture Y, Product Z (forming part of Mixture Y), Z for use as an antihypertensive agent, Process A, Process B, Process C for producing Mixture Y, and Process D for separating X and Z from Y. Due to the invalid priority claim, the effective date for all the subject-matter of EP3 is the filing date of 14 January 2021 because the claim to priority is invalid.

Skou has documentation establishing entitlement to Product X, its use as a medicament, a pharmaceutical composition comprising X, X for use as an antihypertensive agent, Process A, and Process B. Oersted appears to be entitled to Mixture Y, Product Z (forming part of Mixture Y), Z for use as an antihypertensive agent, Process C for producing Mixture Y, and Process D for separating X and Z from Y.

EP3 has not been published, but a copy has been given to Elrond in February 2021. There is no information as to whether this was a confidential disclosure. In any event this will have no impact on EP3 itself.

As with DK1, IN-DG is an unpublished application having a filing date of 15 April 2020, which is earlier than EP3 and if IN-DG gives rise to an application effective in Europe and claiming priority from IN-DG then it will constitute prior art under Art. 54(3) EPC and would destroy novelty of Product X and its use as a medicament if claimed in EP3.

If claimed, X for use as an antihypertensive agent, pharmaceutical preparations comprising X, Mixture Y, Product Z, Z for use as an antihypertensive agent, Process A, Process B, Process C, Process D will be novel and unaffected by IN-DG.

More importantly, DK1 itself is an unpublished application having a filing date of 2 June 2020, which is earlier than EP3, and if DK1 gives rise to an application effective in Europe and claiming priority from DK1 then it will be novelty-only (Art 54(3) EPC) prior art on publication for Product X, its use as a medicament, pharmaceutical preparations comprising X, X for use as an antihypertensive agent and Process A. Mixture Y, Product Z, Z for use as an antihypertensive agent, Process B, Process C and Process D will be novel and unaffected by DK1.

Product Z itself lacks novelty over the 2019 publication of Z as a catalyst in rubber vulcanisation.

Overall, Mixture Y, Product Z for use as an antihypertensive agent, Process B, Process C and Process D appear to be novel with Process B belonging to Skou and Mixture Y, Product Z for use as an antihypertensive agent, Process C and Process D belonging to Oersted.

(iii) Situation with IN-DG

IN-DG has the earliest date of 15 April 2020 for Product X and its use for influencing cholesterol in blood and for Process P. Process P is entirely different to Processes A, B and C. There is nothing to indicate there is any prior art and it seems likely that Product X, its use as a medicine, its specific use for influencing cholesterol in blood, and Process P are all novel and demonstrate an inventive step. At present IN-DG is only an Indian patent

application in the name of DG (Datt Gulati), but the priority year does not expire until 15 April 2021. IN-DG has not been officially published, but Skou has been given a copy in confidence in February 2021.

Question B – What should I do if Mr Oersted agrees to co-operate fully to secure optimal patent protection?

(i) If we want to keep EP3 in force, what steps must be taken and within what time limits

As explained above, the filing and search fees have not been paid and a translation into English, French or German needs to be filed.

With regard to the fees, the EPO will issue a notification of loss of rights (Rule 112 EPC) setting a period of 2 months for payment of the fees under the further processing provisions (Art 121 and Rule 135 EPC). This time limit is not yet known and it is not necessary to wait for the notification. The filing and search fees should be paid together with the fee for further processing (which is 50% of the unpaid fees).

With regard to the translation, if it is not possible to file the translation by 15 March 2021 as noted above, the EPO will issue an invitation to rectify the deficiency within 2 months by filing the translation (Rule 57(a) and 58 EPC). This date is not known at present. If the translation is not filed by the due date set in the invitation, the application will be deemed to be withdrawn and cannot be reinstated with further processing (Art 14(2) and 90(5) EPC).

Because the priority claim is invalid and cannot be corrected, the claim to priority should be withdrawn. This should be done before the preparations for publication are completed and will have the effect of delaying publication until 18 months from the date of filing (i.e., until shortly after 14 July 2022) (Art 93(1) EPC and GL A-VI, 1.1).

In view of the inclusion of the subject-matter of DK1 and of Process B, the application should be corrected to add Skou as co-inventor.

Rule 21(1) EPC and GL A-III, 5.6 permit correction by addition of an inventor by Skou with the consent of the applicant (Oersted), or by Oersted himself as applicant, but it is not clear whether this can be accomplished without payment of the fees because the application is currently deemed to be withdrawn (see GL A-IV, 1.1.1). We should make this correction for a future application in USA.

Although EP3 has been filed by Oersted, subsequent applications claiming priority from EP3 can be filed jointly by Oersted and Skou. Therefore, in this scenario there is no need to correct the applicant for EP3.

(ii) Would it be useful to keep EP3 in force?

EP3 is the earliest date for the subject-matter of Process B which belongs to Skou and for the subject-matter of Mixture Y, Product Z, Z for use as an antihypertensive agent, Process C and Process D which belong to Oersted.

It is important for Skou to secure the filing date of EP3 as a priority date for Process B and it is important for Oersted to secure the filing date of EP3 for his subject-matter. Others may be working in the same field and a copy of EP3 has been given to Elrond without any evidence of confidentiality.

Skou has markets in Europe and USA and EP3 itself would therefore not provide adequate cover. Moreover, Skou has additional subject-matter in that Product X has an anti-viral effect against the herpes, chicken pox and measles viruses for which he requires patent protection.

Therefore, there is no need to keep EP3 in force provided it can be used as a valid basis for a priority claim. In this respect, provided the inventor details can be corrected, EP3 can be allowed to lapse. This seems unlikely in the short term and it will probably be necessary to pay the fees and, possibly, file the translation in order to be able to correct the inventor details. In other respects, there is good reason to file a new (PCT) application with additional subject-matter and claiming priority from EP3 (and DK1) because this would extend the overall period of protection to 20 years from the date of filing the PCT application and EP3 should then be allowed to lapse.

(iii) Should a PCT application be filed?

Yes, an International application should be filed, but not in the form of PCT2 as proposed by Skou. This is also subject to both Skou and Oersted being willing to file an International application as joint applicants and to separate the subject-matter owned by each applicant by filing divisional applications after entry into the National phase. Further divisional applications may be required to cover the different inventions. This will be referred to as PCT-SS.

PCT-SS should be filed as soon as possible because it will include subject-matter that has not yet been part of a patent application and should claim priority from both DK1 and EP3. Because both DK1 and EP3 were filed in Danish, it may be preferable to file PCT-SS in Danish at the Danish Patent Office.

Skou and Oersted should be joint applicants and inventors because both are rightly owners and inventors of part of the intended subject-matter of PCT-SS. The application should include independent claims to:

Product X

Product X for use as a medicament

Pharmaceutical composition comprising X

Process A

(all the above owned by Skou and jointly invented, priority DK1)

Process B

(owned by Skou and jointly invented, priority EP3)

Mixture Y

Mixture Y for use as a medicament

Pharmaceutical composition comprising Y

Product Z in a form suitable for administration to humans and animals

Product Z for use as a medicament

Pharmaceutical composition comprising Z

Process C

Process D

(all owned and invented by Oersted, priority EP3)

With dependent claims to:

Product X, Mixture Y and Product Z for use as an antihypertensive agent and Product X for use as an anti-viral agent, as an anti-herpes virus agent, as an anti-measles virus agent, and as an anti-chicken pox virus agent.

Medical method claims can be included for USA.

Question C – What should I do if Mr Oersted refuses to co-operate in securing patent protection for me?

(i) What legal steps should be taken regarding EP3?

If Oersted refuses to co-operate then he may continue with EP3 or with another application claiming priority from EP3, or he may allow it to lapse.

According to the contract, Oersted could use the information developed under contract and make further improvements based on this information. Therefore, Oersted is inventor and owner of the subject-matter Process C, Mixture Y, Process D and the first and second medical uses of Z in EP3.

However, Skou is joint inventor and sole owner of the subject-matter taken from DK1 and of Process B disclosed in EP3. To secure ownership of this subject-matter from EP3, Skou should commence national entitlement proceedings before the Maritime and Commercial Court in Copenhagen with the aim of obtaining a declaration of ownership which can be filed with the EPO (Art 61(1) EPC). Skou cannot take any action before the EPO in respect of

EP3 at this time other than payment of fees, only Oersted or Carlsberg (Art 133 EPC), and proceedings cannot be stayed until after publication (Rule 14 EPC), so Skou needs to request an urgent injunction requiring Oersted to take all necessary steps to maintain EP3 in force until either proceedings can be stayed or a final decision is issued. This will include paying the fees, filing the translation and withdrawing the priority claim to avoid the need to file a certified copy of DK1 which would clearly demonstrate the invalid nature of the priority claim because it was filed in the name of Skou and not Oersted and there is no evidence that Oersted is a successor in title.

(ii) Would it be useful to keep EP3 in force? Give reasons.

If a final decision on ownership of EP3 can be issued quickly and Skou is found to be the rightful owner of the subject-matter of DK1 and of Process B disclosed in EP3, then Skou may choose to file a new application or to request that the subject-matter owned by him is excised from EP3 (Art 61 and Rule 18 EPC). Because EP3 would be only partly owned by Skou it is not possible to take over EP3 as his own or to request that EP3 is refused as a whole.

In such a case it would be possible to file PCT2, or rather PCT-SS, to include the additional subject-matter relating to anti-viral properties, as mentioned above as planned before 2 June 2021, claiming priority from DK1 and EP3 (or rather a new application filed by Skou under Art. 61 EPC).

However, in practice it is most unlikely that a decision can be issued within this timescale and in any event it does not provide a suitably early date for filing the additional subject-matter. Early protection for the additional subject-matter could be secured by prompt filing of a further Danish patent application directed solely to that subject-matter and identifying Skou as owner and inventor, but it is still unlikely that the entitlement proceedings will be completed by June 2021. The use of Danish being consistent with DK1 and EP3 and therefore potentially cost-effective.

In practice, the only good reason to keeping EP3 alive appears to be to await the outcome of the national entitlement proceedings and to use the final decision to excise the subject-matter of Process B from EP3. Otherwise, EP3 is the earliest disclosure of Process B and could become novelty-only prior art under Art 54(3) EPC against a later European patent application in the name of Skou.

(iii) What further steps could be undertaken to secure protection for the inventions?

It is recommended to file a new International application, PCT2/PCT-SS, in the name of Skou as soon as possible to provide early cover for the anti-viral properties and Process B. It is not possible to claim priority from EP3 because this is not in the name of Skou. Such an application would claim priority from DK1 include independent claims to:

Product X

Product X for use as a medicament

Pharmaceutical composition comprising X

Process A

(all the above owned by Skou and jointly invented, priority DK1)

Process B

(owned by Skou and jointly invented together so Skou, no priority)

With dependent claims to:

Product X for use as an antihypertensive agent, as an anti-viral agent, as an anti-herpes virus agent, as an anti-measles virus agent, and as an anti-chicken pox virus agent.

Medical method claims can be included for USA.

This procedure will give protection in the EP phase for Skou under Art 55 EPC in respect of the apparently non-confidential disclosure of EP3 by Oersted to Elrond in February 2021. The procedure will also give protection under the 12-month grace provisions available in USA.

(iv) Please advise me, in particular in relation to protection in Europe, what arguments speak for the filing of an International application as planned and what arguments – if any – for directly filing instead a European patent application (EP2), in view of the problems with Mr Oersted?

If patent protection is required in both USA and Europe then an International application should be filed. USA will in due course require Oersted's signature or evidence that he has been asked to sign and has not co-operated, but this is not of immediate concern (see PCT Rule 51bis.3).

If speedy grant is desired in either or both of Europe or USA, then direct filing in one or both territories would enable accelerated prosecution (for example under PACE before the EPO).

If speedy grant is not important, then the International route allows more time (30/31 months from earliest priority) to evaluate the various inventions and to assess the markets before incurring the costs of entry into the national phase. The international route also allows more time for resolving entitlement issues.

With regard to overall costs, though, the International route requires fees both in the International phase and subsequently in the national phase and could prove to be more costly in the long term.

The application, either EP2 or an international application corresponding to PCT-SS, should be filed with Skou as sole applicant and Skou and Oersted as joint inventors. It should claim priority from DK1 and be filed as soon as possible, not waiting until the last date of the priority period of 2 June 2021, due to the presence of additional subject-matter relating to the

anti-viral properties of Product X. The need for prompt filing precludes the possibility of claiming priority from EP3. The content should be as in Section C(iii) above.

Question D – Do we have to worry about the Indian patent application IN-DG and what effect could it have on our business in Europe?

As noted above, IN-DG has the earliest date of 15 April 2020 for Product X and its use for influencing cholesterol in blood and for Process P. However, at present IN-DG is only an Indian patent application with no effect in Europe or USA.

If IN-DG enters the European phase with priority from 15 April 2020, on publication it will become novelty-only prior art (Art 54(3) EPC) for Product X and the first medical use of Product X. Moreover, DG could secure patent protection for Product X, its first medical use and its second medical use for manipulating cholesterol. DG will be able to prevent Skou making and selling Product X in Europe for any purpose unless Skou takes a licence, although Skou will have control over its use as an antihypertensive agent and as an anti-viral agent. Depending on the efficiency of Process P in IN-DG it may be possible to negotiate a cross-licence if any of the processes, especially Process B, over which Skou has control is more efficient.