Patents Act 1977 **Opinion Number** **15/20**

OPINION UNDER SECTION 74A

Patent	EP 1854859 B1
Proprietor(s)	Sumitomo Heavy Industries Ltd
Exclusive Licensee	
Requester	Edwards Ltd
Observer(s)	Sumitomo Heavy Industries Ltd
Date Opinion issued	26 October 2020

The request

1. The Comptroller has received a request from Edwards Ltd (the requester) to issue a validity opinion in respect of patent EP 1854859 B1 (the patent) in the name of Sumitomo Heavy Industries Ltd (the proprietor). The request questions the validity of the patent on the basis that certain of the claims are either not novel or lack an inventive step based on submitted prior art documents.

2. The patent is based on a PCT application published as WO 2006/092871 A1 having a filing date of 27 May 2005 and a claim to a priority date of 3 March 2005. The patent was granted on 8 April 2015 and is in force.

3. Observations were received from the proprietor.

4. Observations in reply were received from the requester.

Preliminary Matters

5. One of the principal citations relied on is JP 200507593 (D1). This document was published on 24 March 2005, i.e. between the claimed priority date and the filing date of the patent application. It was cited on the International Search Report and referred to in the examination report issued by the EPO on 19 September 2013. In such circumstances this document might not normally be considered in the opinion as, on the face of it, it had already been considered by the EPO examiner. However, in relation to this document, the EPO examination report suggests no more than that the claim to priority needed to be validated either by filing a translation or making a declaration that the content of the patent application as filed was a complete translation of the priority document. The applicant opted for the latter. It would

appear that the EPO examiner was thereby satisfied that the patent application was entitled to the claimed priority date and D1 was not a valid citation. The requester now makes an apparently new argument in relation to the priority claim, that the priority claim is invalid on the basis of Section 5(3) of the Act. This seems an appropriately *new question* in relation to this document that further consideration in the opinion is warranted.

6. Documents D4 and D5 were also apparently considered by the EPO examiner but these documents are now combined with D3 which is a combination not considered previously.

The patent

7. The patent relates to a cryogenic cooler (cryocooler) for liquefying helium for use for example in magnetic resonance imaging (MRI) scanners. In particular, the patent relates to a regenerative heat exchange material (regenerator) used in the cryogenic cooler.

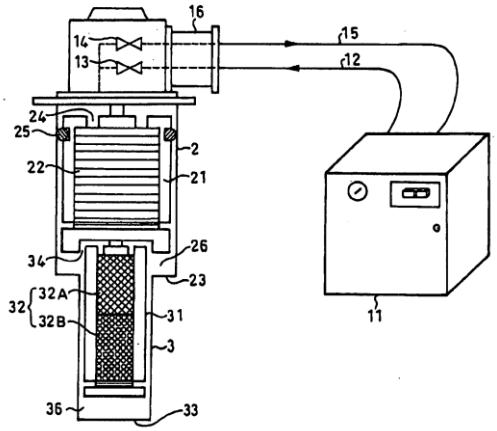
8. Regenerative heat exchange is a type of heat exchange where warm and cold gasses are passed separately in succession over a thermal storage medium (the regenerator). In a first phase the warm gas is passed over the regenerator, giving up its heat to the cooler regenerator so warming the regenerator and cooling the gas. In a second phase the cold gas passes over the regenerator, cooling the regenerator and warming the cold gas. Typically the warm and cold gasses are the same gas. In heating processes regenerative heat exchange may be used to heat incoming air while cooling an exhaust gas. In cryogenic cooling processes the gas is moved across the regenerator before and after compression and expansion, essentially to cool the incoming gas.

9. The main requirements for a regenerator, particularly in cryogenic applications, are that it should have high specific heat capacity, high surface area, low resistance to flow of gas and a low void volume, the latter being required to reduce the amount of gas *trapped* in the regenerator. At the very low temperatures involved in cryogenic applications the specific heat capacity of materials is low and can be anomalous. The requirements for low resistance to flow and a low void volume can be conflicting. For example, to reduce the void volume it may be desirable to have small channels in the material, but this may increase the resistance to flow. These general requirements of regenerators and the necessary compromises are considered to be part of the skilled person's common general knowledge.

10. One aspect of this common general knowledge relates to the use of packed spheres or balls as a regenerator material, as is known in the art. The skilled person would understand that in order to provide suitably sized channels the balls would all have to be reasonably spherical and mostly the same rough size. If they are not spherical or are a mix of sizes then there is a risk the balls will pack too closely together blocking any channels through the matrix.

11. Figure 1 of the patent (below) illustrates a cryocooler comprising the regenerator of the invention. The cryocooler is a GM type cryocooler in which the regenerator itself is moved, causing the gas to pass over it. High pressure helium is supplied via

compressor 11 and valve 13 with valve 14 being provided to return the gas to the low pressure side of the compressor. Valves 13 and 14 are operated sequentially to allow high pressure gas in or low pressure gas out of the cooler. A two stage regenerator is provided having a first stage 21 formed of copper mesh operating at 40K at its lower, cold end, and a second stage 31 operating down to 7K or less. As illustrated, spaces (26, 36) can be seen at the lower end of the first and second stage regenerators into which the regenerator moves in operation as it cycles up and down. The second stage regenerator can be seen to be made of two different materials. The lower material 32B is a magnetic regenerator material comprising holmium-copper (HoCu2). The invention lies in the particular composition of the upper material 32A of this second stage regenerator material as defined by claim 1. In particular, bismuth or an alloy of bismuth and antimony is used rather than lead as is conventional. The description suggests that the inventive material provides a suitable alternative to lead where the use of lead is restricted or forbidden for environmental reasons.



Claim construction

12. As a first step in determining the validity of the patent I must correctly construe the claims. This means interpreting them in the light of the description and drawings as instructed by Section 125(1). In doing so I must interpret the claims in context through the eyes of the person skilled in the art. Ultimately the question is what the person skilled in the art would have understood the patentee to be using the language of the claims to mean. This approach has been confirmed in the decisions of the High Court in *Mylan v Yeda*[1] and the Court of Appeal in *Actavis v ICOS*[2].

13. The skilled person is considered to be a designer of cryocoolers.

14. Claim 1 is the main independent claim and is directed to a regenerator material. Claim 7 is directed to a regenerator filled with the material of claim 1, claim 13 to a cryogenic cooler comprising the regenerator of claim 7, and claims 16 to 21 refer to apparatus including the cryocooler of claim 13.

15. Claims 1 reads as follows:

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[1] *Generics UK Ltd (t/a Mylan) v Yeda Research and Dev. Co. Ltd & Anor* [2017] EWHC 2629 (Pat)
[2] *Actavis Group & Ors v ICOS Corp & Eli Lilly & Co.* [2017] EWCA Civ 1671

A regenerator material comprising a granular body made of bismuth or an alloy of bismuth and antimony, wherein a rate of the granular body having a grain size of 0.14mm to 1.6mm is 70% by weight or more with respect to the entire granular body, and a rate of the granular body in which a ratio of a major axis to a minor axis is 5 or less is 70% by weight or more with respect to the entire granular body.

16. In general, I do not see any issues with the interpretation of this claim. I would however note that the term *comprising* can be taken to mean *including,* and comprising bismuth could be interpreted as just including bismuth. I reject such an interpretation in this instance. I consider it clear from the specification that the regenerator material of claim 1 is substantially entirely bismuth or an alloy of bismuth and antimony.

Prior art

17. Two main pieces of prior art are cited:

D1	JP 2005 075963 A	(SUMITOMO HEAVY IND)	24 March 2005
D3	US 3375867	(DAUNT)	2 April 1968

18. Both these documents relate to cryogenic regenerators. I shall consider each in turn below.

19. D2 – JP 2006 242484 A - is the published priority application of the patent.

20. The remaining documents D4 to D6 are presented in combination with D3 to argue lack of inventive step.

D4	JP 2002 249763 A	(TOSHIBA CORP)	6 September 2002
D5	JP 2004 099822 A	(TOSHIBA CORP)	2 April 2004
D6	“Development of Neodynium and Er 3 Ni Regenerator Materials.” Aprigliano, L. F. et al; Advances in Cryogenic Engineering pp. 1003-1009. Springer, Boston, MA; 1992.		

Priority Date

21. As previously noted, the date of publication of D1 lies between the claimed priority date and the filing date of the patent.

22. The requester argues that the patent is not entitled to the claimed priority by virtue of Section 5(3) of the Act.

23. Section 5(3) reads:

(3) Where an invention or other matter contained in the application in suit was also disclosed in two earlier relevant applications filed by the same applicant as in the case of the application in suit or a predecessor in title of his and the second of those relevant applications was specified in or in connection with the application in suit, the second of those relevant applications shall, so far as concerns that invention or matter, be disregarded unless -

…

24. Following the *unless* is a particular set of circumstances which act to exclude operation of the quoted part. There is no suggestion those circumstances are met in this instance.

25. The effect of this part of the Act is to disregard a priority claim (claimed on the second relevant application) where the invention was also disclosed by the same applicant in an earlier application. It has particular effect when the earlier application was filed more than 12 months before the application in suit such that the earlier application cannot support a priority claim. In those circumstances any priority claim for an invention disclosed in both the earlier application and the second relevant application is lost.

D1 - JP 2005/075963

26. The requester argues that JP 2005/075963 (D1), being filed by the same applicant, constitutes the earlier application, the claimed priority document is the second relevant application and the patent is the application in suit. I agree with that analysis.

27. The question then to be answered is whether the invention of claim 1 is also disclosed in both the earlier application and the second relevant application. On the basis that the patent application was a copy of the priority application, then the invention of claim 1 must be disclosed in the second relevant application. The requester argues further that this invention was also disclosed in the earlier application (D1).

28. The requester refers to the following passages translated (by espacenet) from D1 in support of their argument:

[0019] In this embodiment, the granular bismuth filled as the high temperature side cold storage material 32A can have a purity of 99.99%, for example, and its particle size is 0.01 to 3 mm, preferably 0.1 to 1 mm. More preferably, it is 0.3 to 0.5 mm.

[0020] When the particle size is less than 0.01 mm, the density when filling the regenerator becomes too high, and the passage resistance of the He gas as the cooling medium increases rapidly. Moreover, when a particle size exceeds 3 mm, there exists a possibility that the heat exchange property between a granule and a cooling medium may fall remarkably.

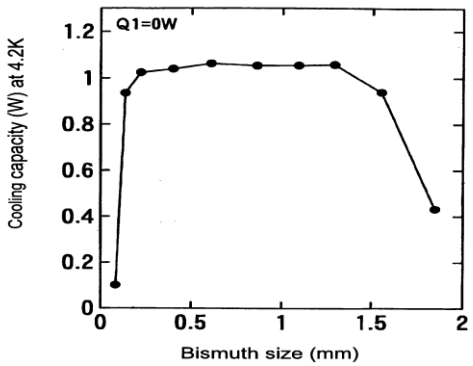
[0021] In addition, the ratio of the maximum diameter to the minimum diameter (aspect ratio) of the bismuth regenerator material of this embodiment is 5 or less, preferably 3 or less, more preferably 2 or less, and spherical as much as possible in any threedimensional direction. It is preferable to approach. When the aspect ratio exceeds 5, mechanical deformation is likely to occur, and it is difficult to fill with high density, so that the cooling efficiency is lowered.

[0022] In the experiment using the 4.2K refrigerator of this embodiment shown below, the bismuth regenerator has a granular shape with a purity of 99.9% or more, a particle size of 0.3 to 0.5 mm, and an aspect ratio of 5 or less. Unless otherwise specified, the operation cycle by the motor 16 is 60 rpm, and the displacer stroke is 20 mm.

29. The requester has suggested that the 99.9% figure in paragraph 22 refers to the percentage of the regenerator which has a particle size of 0.3 to 0.5 mm. I do not consider this to be the case, and I consider that the skilled person would understand this to be the chemical purity of the bismuth. However, I would further consider that the skilled person would interpret paragraph [0022] to be specifying that the predominant composition of the regenerator was a material having a particle size of 0.3 to 0.5 mm and aspect ratio of 5 or less. The specific example of this paragraph of D1 is considered to fall within the scope of claim 1.

30. Nevertheless, this is not a simple anticipation issue. Anticipation only becomes an issue should I consider that the claims of the patent are not entitled to the claimed priority date. To that end I need to establish whether or not D1 discloses the invention of claim 1. If D1 has the technical content that would enable it to support a priority claim (save that it was filed too late) then it discloses the invention. In particular, does D1 disclose sufficient information regarding the ranges involved that it can be considered to be a disclosure of the invention of claim 1? Unfortunately, the parties to the opinion have not provided any argument on this issue.

31. The most specific aspect of claim 1 is the grain size of the bismuth which is required to be between 0.14 to 1.6mm. This range is derived from the graph of figure 2 (reproduced below) which indicates a significant decrease in performance outside this range. It is perhaps worth noting that whilst D1 and the patent share a number of identical figures, D1 does not include this figure.



32. D1 discloses ranges of sizes of 0.01 - 3 mm, 0.1 - 1 mm and 0.3 - 0.5 mm. The first

of these is much broader and the last much narrower, however the middle range overlaps to a considerable extent, albeit that the difference in the upper bound could be considered significant.

33. The most relevant case law to determine whether or not this is a disclosure of the invention appears to be the decision of the Court of Appeal in *Pharmacia Corp v Merck & Co.*[3] Aldous LJ had the following to say (my emphasis):

> *101. …The invention of the priority document, namely the broad class of compounds in formula 11 and class in formula 1 is not the same as in the application.* ***The disclosure of the broad class and the subclass without more cannot support the selection of another subclass*** *as having anti-inflammatory activity and COX II selectivity which is the invention of the application.* ***Of course it is possible to claim in a patent a narrower range of compounds than that disclosed in the priority document. But the fact that it is a narrower range does not mean that there is support for that range****. What is required, as Lord Hoffmann pointed out in Biogen, is that the priority document must contain sufficient material for the priority document to constitute the enabling disclosure of claim 1.*

34. It seems arguable that the ranges of the patent and D1 correspond to the subclasses referred to in the quote, with D1 disclosing a broad range and a sub-range and the patent disclosing a different sub-range. Such an argument might suggest that D1 does not disclose the invention of the patent.

35. However, having developed this analysis so far I do not think I can continue in the absence of appropriate argument from the parties. Suffice to say, I do not consider that the requester has made the case that D1 discloses the invention of the patent.

36. Accordingly, based on the argument provided, I consider that claim 1 of the patent is entitled to the claimed priority date and D1 is not a valid citation in relation to it.

37. The requester has further argued that claims 7 to 10, 13, 14, 16 to 18 are also anticipated by D1. When issues of priority dates arise, it is possible that an independent claim is entitled to a claimed priority date but a dependant claim is not. This can give rise to the somewhat surprising situation in which an independent claim is valid but a dependent claim is not. Such a situation might have arisen in the present case if, for example, there had been a claim to the narrow range of 0.3 to 0.5 mm, but there is no such claim. On the face of it all the claims are entitled to the claimed priority date and none are therefore anticipated by D1.

D3 – US 3375867

38. The invention of D3 is directed to a regenerator material comprising a lanthanide metal. This aspect of D3 is not relevant to the patent.

39. D3 describes the background to the invention and conventional arrangements in the

[3] *Pharmacia Corp. v Merck & Co. Inc.* [2002] RPC 41

following terms:

> *A survey of materials suitable for regenerator matrices shows that, for example, below about 50K, gold, bismuth and lead show values of C larger than that of copper and bronze. Figure 1 depicts a plot of observed values of C versus T for gold, copper, lead and bismuth. It will be noted that below 40K lead has the largest C values. For this reason, the use of lead as a matrix material for very low temperature regenerators has been common for some time (e.g. as in patent US 2,966,035) and its use has generally been in the shape of small balls of about 0.01 to 0.10 inch [0.25 to 2.5 mm] in diameter. However, there are other solid materials than lead which may be used as matrices in very low temperature regenerators, and this invention encompasses the use of all solid matrix materials which may be formed and shaped.*
>
> *According to the present invention, highly desirable matrix materials are obtained from solids which have a reversible magnetic transformation occurring in the temperature range of about 4K to about 30K. As can be seen from the accompanying Figure 1, at above 30K, the more common materials, such as lead, gold, copper and bismuth, which do not undergo such transformations, are adequate for the purpose. Among the materials having characteristics found suitable for the present invention are the rare earth metals …*

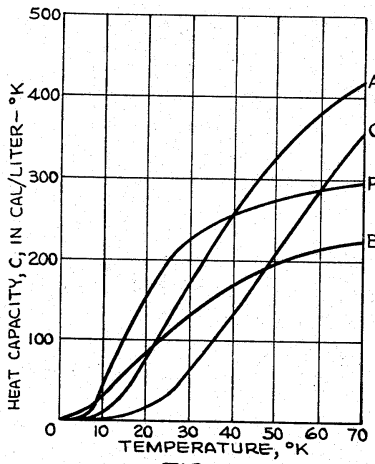


FIG. 1

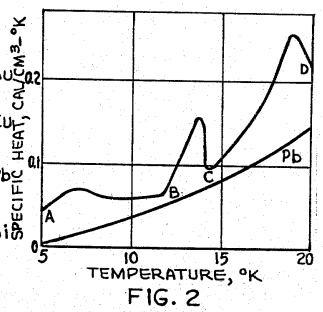


FIG. 2

40. The only specific example provided in this disclosure is the use of lead balls of sizes in the range 0.25 to 2.5 mm.

41. There is a suggestion that Bismuth may be a suitable alternative to lead, but there is however no specific disclosure of the use of Bismuth balls of any size and D3 does not therefore anticipate the claims. I would add that forming the Bismuth as balls would not seem to be implicit as the use of wire mesh or gauze regenerators is well known. See, for example, figure 3 of D3 and the conventional copper mesh first stage regenerator of D1.

Inventive step

42. Nevertheless, I consider that it would be obvious to use Bismuth balls in place of lead balls, and furthermore that it would be obvious that the balls are generally the same size as each other and generally spherical.

43. D3 however relates to a range of sizes from 0.25 to 2.5 mm, whilst the patent is directed to a selection of sizes of bismuth balls of 0.14 to 1.6mm. On the basis of the significant overlap this appears on the face of it to be a selection invention.

44. The Manual of Patent Practice sets out guidance for determining the inventiveness of selection inventions at paragraph 3.89, based on the decision of the Court of Appeal in *Generics [UK] Ltd v Yeda Research and Development* [2013][4], as follows:

    i) Article 56 of the EPC is in part based on the underlying principle that the scope of the patent monopoly must be justified by the patentee's contribution to the art;

    ii) If the alleged contribution is a technical effect which is not common to substantially everything covered by a claim, it cannot be used for the purposes of judging obviousness;

    iii) In such circumstances the claim must either be restricted to the subject matter which makes the technical contribution, or a different contribution common to the whole claim must be found;

    iv) A selection from the prior art which is purely arbitrary and cannot be justified by some useful technical property is likely to be held to be obvious because it does not make a real technical advance;

    v) A technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step;

    vi) Later evidence may be cited to support a technical effect made plausible by the specification;

    vii) Provided the technical effect is made plausible, no further proof of the existence of the effect is to be demanded of the specification before judging obviousness by reference to the technical effect put forward.

45. As a first step to establishing the inventiveness of the selection it is necessary to determine if there is a technical effect associated with this range of sizes or whether it is just an arbitrary range.

46. The proprietor appears to be making the case that it is a selection invention in their observations referring to the range being specific to bismuth and the significant decrease in cooling capacity outside this range as follows:

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[4] *Generics [UK] Ltd (t/a Mylan) v Yeda Research and Development Co. Ltd & Anor*. [2013] EWCA Civ 925

The feature of claim 1 of the patent that "a rate of the granular body having a grain size of 0.14mm to 1.6mm is 70% by weight or more with respect to the entire granular body", is a range specific to bismuth, and as is seen from Fig. 2 of the patent, there is a significant decrease in cooling capacity in a range outside the claimed range. Although the claimed grain size range overlaps the diameter range of lead of D3, namely, about 0.01 to 0.10 inch (0.254 mm to 2.54 mm), the diameter range of lead of D3 includes a range where the cooling capacity of bismuth significantly decreases.

47. In response, the requester highlights the passage at paragraph [0049] of the patent which states *"These results consider that the cooling capacity is not influenced by the grain size of bismuth in the evaluated range…",* and suggests that this is a claim that the size has no technical effect. This paragraph however relates to graphs presented in figures 9 to 11 which present results of experiments carried out to evaluate the cooling capacity of bismuth balls having sizes of 0.3 to 0.7 mm. The results merely restate what is shown in figure 2, that there is no difference in cooling capacity across this range of evaluated sizes.

48. As stated by the proprietor, it is apparent from figure 2 of the patent that the size range claimed has a technical effect, and that outside this range the cooling capacity of bismuth balls is significantly decreased. Based on the tests set out in *Generics v Yeda*, this technical effect appears to be one based on a useful technical property such that account may be taken of it in determining inventive step. It is not just an arbitrary selection which would likely be obvious.

49. No further evidence is provided to suggest that the range is obvious. Therefore, insofar as claim 1 may be considered a selection invention, the range of claim 1 is inventive in relation to the range of D3.

50. Nevertheless, it may be the case that it is obvious to use bismuth balls of a particular size that falls within the range of claim 1. The requester makes the following further arguments in their observations in reply, in relation to the sizes of balls that might be obvious:

The skilled person would be aware from the prior art that the choice of grain size is a compromise between pressure drop and heat transfer, smaller spheres providing a denser environment and thus, a higher pressure drop, but also a larger surface area to volume ratio and thus, provide improved heat transfer. Document D5 discusses this compromise in the paragraphs abridging pages 5 and 6. Document D6 in the first paragraph on page 6 also discusses the compromise between too small particles and those that are too large and notes that a powder size of 0.23mm diameter is considered optimum for a regenerator matrix in a regenerative heat exchanger. The skilled person would therefore understand the effect particle size has on performance and would select an appropriate grain size according to the requirements and pressures and temperatures used and would do so by testing the performance of different grain sizes such as those disclosed as optimum by D6, or ones within the ranges suggested by D3 or D5. He would therefore arrive at the particle size of the claims without the exercise of inventive skill. Furthermore, he would recognise that when selecting a preferred particle size it is preferable that most of the particles indeed 70%

or more have that particle size as this is disclosed in D5.

51. I do not consider that using the whole of the ranges of sizes quoted in either of D3 (0.25 – 2.5 mm) or D5 (0.01 to 3mm) would be obvious to the skilled person.

52. Although the relevant part of D3 is said to be a discussion of conventional arrangements, I do not consider I can take it at face value without further evidence. I am somewhat sceptical that such a relatively wide range represents real conventional arrangements. The skilled person reading this part of D3 would read it with their common general knowledge and interpret it accordingly. They would only acknowledge as conventional that which fell within their common general knowledge. If they were to consider replacing lead balls with bismuth balls, then I consider they would choose a size for the bismuth ball which was conventional for a lead ball. There is nothing in D3 to point towards choosing a size which falls within the range disclosed in claim 1.

53. D5 relates to a rare earth magnetic material regenerator. There is nothing to suggest that the skilled person would consider the sizes disclosed in this document when considering what size bismuth balls to use to replace lead balls in a regenerator.

54. Figure 1 of D6 illustrates a typical regenerative matrix of a GM cryocooler and it is stated (page 2) that *"A typical regenerative matrix consists of lead shot measuring 0.23 mm in diameter."* Page 6 of D6 also states *"A powder size of 0.23 mm diameter is considered optimum for a regenerator matrix …"* Such statements may more accurately reflect the skilled person's common general knowledge than the range referred to in D3. However, this being the only evidence provided suggesting 0.23 mm is optimum, I do not consider I can rely on it as proving on the balance of probabilities that it is common general knowledge. As well as just being a single document, this figure is also at the very lower limit of the range disclosed in D3 such that the two documents do not strongly support one another. I also note that D6 was only raised in relation to claim 5 in the opinion request and the proprietor has not therefore been afforded a proper opportunity to rebut this later argument. As such I do not consider that D6 on its own supports an assertion that it would be obvious to form bismuth balls for a regenerator with a diameter of 0.23 mm. If, through further evidence, it could be established that the use of 0.23 mm lead shot was well known and formed part of the skilled person's common general knowledge, then it would seem that using similar size bismuth balls was obvious.

55. In summary, the evidence provided by the requester is not considered to demonstrate that, on the balance of probabilities, it would be obvious to use bismuth balls having a specific diameter somewhere between 0.14 to 1.6 mm as a regenerator material. Nor is the range obvious in spite of the overlap with the range disclosed in D3.

56. Consequently claim 1 of the patent is considered inventive.

57. As I have found claim 1 to be inventive then the remaining claims which are all dependant from it are also inventive.

58. I should mention briefly the construction of claim 6 as, whilst it refers back to claim 1, the requester has suggested it is quite different in scope. Claim 6 reads:

6. The regenerator material according to any of claims 1 to 5, wherein the granular body made of bismuth or an alloy of bismuth and antimony is sintered and processed into a block form, a pellet form or a plate form.

59. I would agree with the requester that this has a somewhat different scope. The skilled person would construe this claim as a product by process claim directed to a block, pellet or plate formed by sintering the material of claim 1. Product by process claims are interpreted as claims to the product per se and do not derive novelty or inventiveness from the process. No argument has however been put forward that any of the documents disclose such a product.

Opinion

60. Based on the argument and evidence provided it is my opinion that the claims of EP 1854859 are novel and inventive. The patent is therefore valid.

61. In particular, D1 is not a valid citation having regard to the accompanying argument, and claim 1 is novel and inventive in relation to D3 based on the argument and evidence provided.

Matthew Jefferson
Examiner

NOTE

This opinion is not based on the outcome of fully litigated proceedings. Rather, it is based on whatever material the persons requesting the opinion and filing observations have chosen to put before the Office.