

comprise tubing which is partially filled with a liquid cryogen, such that droplets of liquid cryogen are separated by bubbles of vapour cryogen. In particular, the PHPs have an evaporator region, in which the cryogen is heated due to its proximity to the superconducting magnet assembly. The PHPs also have a condenser region, in which the cryogen is cooled. Heat transfer occurs due to the vapour bubbles being generated and/or growing in the evaporator region, and shrinking in the condenser region. This causes liquid cryogen to be transported by thermally induced, self-excited oscillations, thereby providing cooling to the superconducting magnet.

The law

- 6 Section 14(3) of the Patents Act requires that:

The specification of an application shall disclose the invention in a manner which is clear enough and complete enough for the invention to be performed by a person skilled in the art.

- 7 In his examination reports, the examiner points to relevant case law which is discussed in the *Manual of Patent Practice*. The case law explains that the disclosure must be sufficient to enable the whole width of the claimed invention to be performed (*Biogen Inc v Medeva plc* [1997] RPC 1). Performing the invention must be possible without requiring the skilled person to find out anything new (*Edison and Swan Electric Light Co v Holland*, 6 RPC 282), or to perform tests or developments that go beyond routine trials (*Halliburton Energy Services Inc v Smith International (North Sea) Ltd* [2006] RPC 2), or to go to the expense and labour of trying to ascertain which products encompassed by a claim actually have the required properties (*American Home Products Corp. v Novartis Pharmaceuticals UK Ltd* [2001] RPC 8).
- 8 Although not expressly cited by the examiner, this position appears to be summed up neatly in *Novartis AG v Johnson & Johnson Medical Ltd* [2010] EWCA Civ 1039, where the Court of Appeal upheld a finding of insufficiency because “the instructions do not enable the skilled person readily to perform the invention over the whole area claimed without undue burden and without needing inventive skill”.
- 9 I also note that guidance was given by the House of Lords in *Kirin-Amgen Inc v Hoechst Marion Roussel* [2005] RPC 9, where it was held that the first step in determining whether the specification is sufficient or not was to identify the invention and decide what it claimed to enable the skilled man to do. It was then possible to ask whether the specification enabled him to do it.
- 10 I did not detect, in the written responses to the examiner’s reports or in the submissions made in relation to the hearing, that the applicant has any dispute with the relevance of the principles relating to sufficiency set out in case law. The matters in dispute relate to whether the applications, on their facts, satisfy the legal requirement as interpreted by the courts.

Arguments and analysis

- 11 The examiner maintains that the applications do not sufficiently disclose how a skilled person could use cryogenic PHPs to make a working superconducting magnet assembly as claimed. His position is summarised for each application in his

pre-hearing report of 28 January 2014 and more fully in his examination report of 17 December 2013.

- 12 The applicant's arguments are contained in its responses of 28 May 2013, 29 November 2013 and 17 January 2014, with further arguments being set out at the hearing. The attorney also filed some further academic documents in support of the applicant's case on 25 March 2014, just before the hearing, and a short letter and witness statement was filed after the hearing, on 15 May 2014.
- 13 What I must do is determine, in light of all this material and the arguments before me, whether the specifications disclose their respective inventions in a sufficiently clear and complete way, within the meaning of the relevant law.

Identifying the inventions

- 14 The latest claim set for 556 was filed on 17 January 2014 and it comprises one main independent claim which reads as follows:

A superconducting magnet assembly comprising:

a coil former;

at least one superconducting solenoid magnet comprising at least one superconducting winding wrapped about the coil former and configured to generate a magnetic field; and

first and second two-phase heat transfer devices thermally connected to the at least one superconducting solenoid magnet, said first and second heat transfer devices comprising respective tubing containing liquid and vapor cryogen therein, said liquid forming a plurality of droplets separated by bubbles of said vapor cryogen, the first heat transfer device being provided at a periphery of the coil former and the second heat transfer device being provided at an interior bore of the coil former;

wherein the cryogen comprises one of helium 4, helium 3, hydrogen, neon, nitrogen, oxygen, argon, krypton, and combinations thereof; and

wherein a liquid portion of the cryogen fills a percentage of a total volume of the at least one two-phase heat transfer device in a range from 10% to 90%.

- 15 The invention identified by claim 1 is therefore a superconducting magnet assembly, which includes one or more superconducting solenoid magnets and a pair of two-phase heat transfer devices which are thermally connected to the magnet(s). The two-phase heat transfer devices comprise tubing which contains liquid droplets of cryogen separated by vapour cryogen bubbles. One of a number of cryogens, or a combination, can be used. One heat transfer device is at the periphery of the coil former of the magnet(s) and the other is in an interior bore of that former.
- 16 I note that there appears to be an issue with the clarity of the claim, because the final paragraph refers to "a liquid portion of the cryogen fills a percentage of a total volume of **the at least one** two-phase heat transfer device in a range from 10% to 90%". This suggests that there is an antecedent for having "at least one" heat transfer device, and so that there could be only one such device. However, the earlier part of the claim is clearly directed to an assembly with "first and second two-phase heat transfer devices". I do not think this issue materially affects the identification of the invention for the purposes of this decision, and I shall assume

that the claimed two heat transfer devices contain liquid cryogen by volume within the percentage range claimed.

- 17 It is also interesting to note that the claim does not explicitly refer to a PHP. It does not state that the heat transfer device has evaporator and condenser portions, but it does refer to a heat transfer device comprising tubing with liquid droplets and vapour bubbles of cryogen contained in it. It seems to me that the applicant's attorney and the examiner have proceeded on the basis that the heat transfer device of the claim, with the features set out in the claim, will function as a PHP (i.e. thermally induced self-excited oscillations will occur and thus heat will be transferred). Reading the claim in light of the specification as a whole, I am prepared to proceed on the basis of that construction. However, references such as that in the last line of page 3 of the specification (which suggests that a PHP is just one example of a two-phase heat transfer device of the invention) and in line 10 of page 4 (which suggests that tubing is just one example form of a PHP) seem to need to be addressed.
- 18 The latest claim set for 558 was also filed on 17 January 2014 and it comprises two main independent claims, namely claim 1 and claim 7. Claim 1 is directed to a method of manufacturing a superconducting magnet assembly. However, claim 7 is the broadest and reads as follows:

A superconducting magnet assembly comprising:

a housing containing a first vacuum reservoir therein, the housing further containing:

a coil former therein;

a plurality of magnets located within or adjacent to the coil former to receive an object;

a second vacuum reservoir having a cryogen reservoir therein;

a cryocooler in the second vacuum reservoir and in thermal communication with the cryogen reservoir; and

a two-phase heat transfer device comprising:

a pulsating heat pipe comprising tubing containing liquid and vapor cryogen therein said liquid forming a plurality of droplets separated by bubbles of said vapor cryogen, the tubing including an evaporator region and a condenser region;

wherein the evaporator region of the two-phase heat transfer device is in thermal communication with one of the coil former and the plurality of magnets and the condenser region of the two-phase heat transfer device is in thermal communication with the cryogen reservoir;

wherein the liquid and vapour cryogen in the tubing of the first and second two-phase heat exchangers comprises one of helium 4, helium 3, hydrogen, neon, nitrogen, oxygen, argon, krypton, and combinations thereof; and

wherein the liquid cryogen fills a percentage of a total volume of the tubing of the two-phase heat transfer devices in a range from 10% to 90%.

- 19 The invention identified by this claim is a superconducting magnet assembly comprising a plurality of superconducting magnets, and with a two-phase heat transfer device. This heat transfer device comprises a PHP with evaporator and

condenser regions, and which has tubing containing liquid droplets of cryogen separated by vapour cryogen bubbles. The evaporator region is thermally connected to the magnets or coil former, and the condenser region is in thermal connection with a cryogen reservoir. The percentage of liquid cryogen in the tubing is within a given volume range.

- 20 I note what seems to be a clarity issue here as well. The penultimate paragraph refers to “the liquid and vapour cryogen in the tubing of **the first and second two-phase heat exchangers** comprises one of helium 4, helium 3, hydrogen, neon, nitrogen, oxygen, argon, krypton, and combinations thereof”. However, the rest of the claim is clearly directed to an assembly with a single heat transfer device. I do not think this issue materially affects the identification of the invention for the purposes of this decision. I shall assume that one of the cryogens referred to in that paragraph, or a combination of them, can be used in the single heat transfer device referred to in the rest of the claim.
- 21 Independent claim 1 of 558 relates to a method of manufacturing a superconducting magnet assembly having analogous features to claim 7, but which also includes the additional steps of providing a thermal shield surrounding the coil former in the first vacuum reservoir, and providing a second two-phase heat transfer device which is thermally connected with the thermal shield and the cryocooler.
- 22 In summary, then, although there are some differences in features of the two inventions as claimed, and there are a few clarity issues, it can be seen that the two sets of claims identify inventions each of which are concerned with a superconducting magnet assembly, or a method of manufacturing such an assembly, and in which at least one heat transfer device in the form of a cryogenic PHP is thermally connected to the superconducting magnet(s) of that assembly. The percentage of liquid cryogen in the PHP is between 10 and 90%, and one of a number of cryogens, or a combination, can be used.

What the inventions claim to enable the skilled man to do

- 23 I do not think there can be any doubt that a claim to a “superconducting magnet assembly” must be directed to an assembly which works successfully, and which achieves the cooling necessary to get the magnet windings to function in their superconducting state. Therefore, what both 556 and 558 claim to enable the skilled man to do is successfully to cool one or more superconducting magnets, within a superconducting magnet assembly, by using the cryogenic PHP(s) with the claimed features.
- 24 I should note that I asked the attorney at the hearing if there was any material difference between the two applications in terms of the sufficiency question I must decide. He conceded that in his view there was not, and agreed that the applications would stand or fall together.
- 25 It is appropriate at this point to consider who the skilled man is. At the hearing, in the context of discussing the contribution made by a particular individual in the team, the attorney suggested that the skilled man might be a graduate student working in a research environment in the cryogenic field. I am cautious about accepting this proposition, not least because the skilled man is a notional legal construct with no

capacity for invention, and the example given was not only a real individual but someone closely involved with the inventor.

- 26 Nevertheless, having considered this point further and having read the considerable amount of academic material provided in relation to this case, it seems reasonable to me to proceed on the basis that, in this highly specialised field, the skilled person is likely to be a reasonably highly-qualified laboratory technician or similar, who is familiar on a technical or scientific level with the cryogenic environment, and the equipment and technical challenges involved when working in that environment.

What the specifications enable the skilled man to do

- 27 One difficulty in deciding this matter is the lack of information before me about the state of the art at the priority date. Clearly this has a bearing on determining what the specification teaches the skilled man that he did not know before.
- 28 The hearing was a chance to explore this point further, and Mr Stautner helpfully explained that the detailed theory underpinning how PHPs work is not well understood, but that it has been known for some years that they can operate efficiently at room temperature (using water, for example). I also understood him to say that it occurred to him in 2005 that it may be possible to make a cryogenic PHP, and that it took another 2 years to get that work off the ground. It was said that use of a PHP at cryogenic temperatures was not publically known at the priority date. Mr Stautner also commented on how cryogenic fluids behave in a very different way from water at room temperature, and how choosing the right capillary size, pressure and other parameters for any given particular cryogen would be necessary.
- 29 It was helpfully clarified that the condenser and evaporator apparatus described in the specifications were conventional, and also that the description near the bottom of page 7 of 556 (and page 11 of 558), describing in general terms how cooling occurs by virtue of the generation and growth of bubbles in the evaporator region and concomitant shrinking in the condenser region, reflected at a general level the skilled person's understanding of how a PHP operates (although, as noted above, the detailed theory remains not well understood).
- 30 However, the examiner explains (for example in his examination report of 17 December 2013) that his argument is not focussed on whether or not a cryogenic PHP can be constructed at the priority date. Rather, his point is that it was a well-known aim to use a cryogenic PHP for the purpose of superconducting magnet cooling, but that it was not straightforward to achieve. The examiner's view is that the specifications do not disclose sufficiently how the skilled person could use a cryogenic PHP to make a working superconducting magnet assembly.
- 31 Therefore, he says, it is not clear how the skilled person would have been able to put the claimed invention into practice, in terms of achieving the desired cooling of a superconducting magnet assembly. Furthermore, the examiner points to the range of options presented and is of the view that it would require expense, labour and prolonged research, beyond routine trials, to identify which options would work in terms of magnet cooling. The applicant of course disagrees.

- 32 The arguments centre on a number of academic papers and related conference material. The examiner and the attorney hold differing views as to what these documents show about the state of the art and the ease with which the invention could be implemented. A witness statement provided after the hearing also goes to these points.
- 33 The examiner's view is that these papers and other material support his sufficiency objection. He points to the documents which show "conceptual illustrations" of a superconducting magnet using a PHP, and which are aimed at achieving this goal, but which show that no practical arrangement has been constructed in which a superconducting magnet has been successfully cooled and operated using a cryogenic PHP. He acknowledges that the documents are all dated after the priority date but his point is that, if this was still an unachieved aim for some years after the priority date, then it cannot have been possible (on the basis of the disclosure in the specifications, at least) for the skilled person to have carried out the claimed inventions at the priority date without "significant expense, labour and prolonged research".
- 34 In written replies to the examiner, the attorney states that "the inventor knows of several such devices that had been constructed" and that a "practical PHP-type device" had been constructed "by the date referred to by the examiner". In support of this, the attorney relied on the same (and some other, similar) academic documents relied on by the examiner.
- 35 This point was elaborated at the hearing. The attorney's argument, in essence, was that the academic documents all show that a working cryogenic PHP was entirely achievable and had been achieved in the period following the priority date. "We've done it", he said "and so have others". In particular, he pointed to drawings within some of the papers which show a superconducting magnet with a cryogenic PHP incorporated, and to references in the papers which confirm the stable operation of cryogenic PHPs.
- 36 The attorney also raised some wider arguments at the hearing in relation to the relevance of the academic papers (and he made clear that, in any case, he regarded these papers as "secondary evidence at best"). He argued that it is immaterial whether a PHP for a superconducting magnet has actually been constructed. The question, he said, is whether or not the skilled person could implement the invention on the basis of the disclosure, not whether they actually did so.
- 37 He also put forward a number of reasons, other than difficulty, why successful use of a cryogenic PHP to cool a superconducting magnet may not have taken place or may not have been disclosed. These included lack of funding, awareness of possible intellectual property, or work on commercialisation or optimisation being done in confidence. He also pointed out that the further commercialisation and optimisation being shown in the various papers may have been done with a view to commercial development – and so it did not mean necessarily that further invention was needed in order to get a cryogenic PHP to cool a superconducting magnet. It could have been that, for such reasons, the teams working on this had chosen not to take that step yet.

- 38 After the hearing, the Office wrote to the applicant on 2 May 2014 in order to give an opportunity to provide further brief submissions and potentially evidence in relation to the state of the art specifically at the priority date. This was also an opportunity to provide evidence and further submissions in relation to an email mentioned at the hearing, which was said to disclose the ease with which the invention was implemented. The resulting witness statement provided on 15 May 2014 was from Luis Diego Fonseca, a PhD student at the University of Wisconsin who was previously engaged on a GE Global Research-sponsored project at that University to characterise the properties of cryogenic PHPs.
- 39 In his witness statement, Mr Fonseca explains that he was offered the position on the research project in September 2011, with the aim of making a cryogenic PHP and characterising its operating properties, in particular its thermal efficiency. This PHP is said in the statement to have been “in essence as per those taught by the teachings of [certain US patent applications] which correspond substantially to equivalent UK patent applications GB 2 469 176 and GB 2 469 717” (i.e. the applications in suit). Mr Fonseca says that certain issues were “quickly resolved” by using “off-the-shelf capillary tubes” and removing some leaking pressure sensors, and he then made a cryogenic PHP which “functioned extremely well...at an operating temperature of 4.2 Kelvin”.
- 40 The statement goes on to say that Mr Fonseca did not make a superconducting magnet that incorporated the cryogenic PHP, but he was well aware that “the ultimate goal was to eventually use the cryogenic PHP in a superconducting magnet of a nuclear magnetic resonance imaging (MRI) scanner”. He summarises the position as follows: “I thus experienced no major insurmountable technical difficulties when making the aforementioned cryogenic PHP that would lead me to believe that a working, if not necessarily fully-optimised, cryogenic PHP for a superconducting magnet could not be made when respectively considering the teachings of [the applications in suit]”.
- 41 The academic papers range from 2009 to 2014, and all are concerned with developing, testing, understanding and characterising cryogenic PHPs. Having considered them all, I agree with the attorney that the material demonstrates that the construction of working cryogenic PHPs has been achieved since the priority date. The material also shows how various aspects of their performance and characteristics have been investigated and determined in detail. It is also clear that the work done in most, if not all, of the papers is done with the intention that such devices can be used to cool superconducting magnets.
- 42 However, I also agree with the examiner that none of the material appears to show that a cryogenic PHP has actually been used to cool a superconducting magnet. Drawings of any such arrangements are consistently referred to as “conceptual” and cryogenic PHPs are sometimes referred to as “prototypes” which are used to determine the “feasibility” of use to cool superconducting magnets. Other references are to such use being “promising”. One paper – *Mito et al* (2012) – discusses how the next stage in their work will be to build a dummy magnet with a built in PHP, for a “cryogenic demonstration test”. The overall impression is of careful progress, as the understanding of the properties and characteristics of cryogenic PHPs moves on, towards the actual use of cryogenic PHPs for cooling superconducting magnets.

- 43 The witness statement is consistent with the picture which emerges from the academic papers and supports the view that, at some point after the priority date, a working cryogenic PHP was made but was not used to cool a superconducting magnet.
- 44 It is clear that there has been much work since the priority date involving the careful further characterisation of cryogenic PHPs, measurement and testing, and optimisation of their performance. But, looking at matters from the priority date, does this work amount to a significant step which was essential for the skilled man to take, in order to get a working cryogenic PHP successfully cooling a superconducting magnet assembly? One aspect of this question is to ask whether the further work which has taken place subsequent to the priority date was essential in order to get the invention to work at all, or whether the invention would have worked at the priority date (at least sub-optimally) without this further work. If this further work was essential in order to get the invention to work, a further point is whether that essential work amounted to routine trials and development, or something more.
- 45 Because of the amount of further work which appears to have been done since 2009, and the apparent fact that no-one has actually used a cryogenic PHP to cool a superconducting magnet despite that work, one could surmise that it must have been essential to do that work (and it perhaps remains essential to do more) before being able to use a cryogenic PHP to cool a superconducting magnet.
- 46 However, the applicant says that this further work is not essential to get the invention to work, at least sub-optimally; that all the ranges disclosed in the specifications work, and points out that it is not a requirement of UK law to disclose the “best mode” of embodying the invention.
- 47 I also see some force in the attorney’s point that there may be a number of reasons why particular researchers have not yet moved to the point of actually using a cryogenic PHP to cool a superconducting magnet, and that these reasons are nothing to do with an inability to work the invention at the priority date. It seems to me there is considerable doubt as to the reason(s) for non-connection of a cryogenic PHP to a superconducting magnet at this stage, and whether that step has not been taken because of the need to characterise further and test PHP properties or because of a desire to optimise performance before going ahead further, or for reasons concerned with potential commercialisation and the wider research programme, or for other reasons.
- 48 A part of the difficulty here come backs to the fact that I have not had the benefit of very much direct evidence at all as to the state of the art at the priority date itself. Further doubt must be created when trying to make a finding of fact about what could or could not have been achieved at the priority date by using evidence of what actually has been achieved some time after that date. This relates to the attorney’s submission, with which I agree, that sufficient disclosure exists if the skilled person could have made the invention at the priority date. It is not necessary to show that it was actually made.
- 49 Furthermore, I think there is considerable doubt as to whether, on the basis of the material I have before me, the testing, optimisation and characterisation that has taken place could have been said, at the priority date, to amount to something more

than routine trials and development of the invention, which would be carried out by the skilled person that I have identified above. I do not think the material before me give me much assistance at all on this question. The disclosure would not be insufficient if this testing and characterisation did not in fact amount to more than routine trials and tests.

- 50 Considerable doubt exists for all the reasons set out above. Furthermore, since these are all questions of fact not law, on which a court would benefit from expert evidence that I do not have, the applicant is entitled to the benefit of that doubt. Therefore, I do not think I should conclude that the reason for non-connection of a cryogenic PHP to a superconducting magnet since 2009 has been because further significant work or invention has been required in order to get to that point. It follows that I do not think it would be right for me to conclude that the specifications would not have enabled the skilled person to use a cryogenic PHP to cool a superconducting magnet assembly – at least non-optimally. The examiner's objection to insufficiency, made on the basis of the material before me, should not be maintained.

Conclusion

- 51 I conclude that the examiner's objection to insufficiency should not be maintained. The application is remitted to the examiner for him to consider any outstanding matters, including the claim clarity points discussed in this decision.

Dr J E PORTER

Deputy Director acting for the Comptroller