2019 Study Question

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Plausibility

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I. Current law and practice

Please answer all questions in Part I on the basis of your Group's current law.

1. Does your law in general provide a plausibility requirement?

   Yes

   Please Explain

2. Is the plausibility requirement if any a stand-alone requirement or is it integrated into another requirement (e.g. inventive step)?

   No

   Please Explain

   There is no 'yes' or 'no' answer to this question.

   The plausibility requirement or “standard” is integrated into other requirements; it is not a stand-alone requirement. As Lord Sumption said in the Supreme Court decision of Warner-Lambert Company LLC v Generics (UK) Ltd [t/a Mylan] [2018] UKSC 56 at [36]:

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“Plausibility is not a distinct condition of validity with a life of its own, but a standard against which that must be demonstrated.”

Under UK law, the plausibility requirement is more pervasive than in the European Patent Office (EPO) where it has arisen in the context of obviousness and sufficiency. In the UK, plausibility has come up in the context of priority (enablement), novelty, inventive step, insufficiency, industrial application and lack of support. The relevant case law is discussed in the answers to questions 5 and 6.

3. Are there any statutory provisions that specifically apply to plausibility? If yes, please briefly explain.

No

Please Explain

The concept of plausibility under English law is judge-made (following closely the approach developed by the EPO), but its foundation is rooted in the justifications for the statutory requirements, in particular the need for patents to make a technical contribution to society.

4. Please briefly describe the general patentability requirements in the statutory law of your jurisdiction that are or would be relevant to the issue of plausibility.

For an invention to be a patentable invention, **div 1** of the Patents Act 1977 provides that it must:

- be new, in that it does not form part of the state of the art (**s2** Patents Act 1977 (Novelty));
- involve an inventive step, in that it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art (**s3** Patents Act 1977 (Obviousness)); and
- be capable of industrial application in that it can be made or used in any kind of industry, including agriculture (**s4** Patents Act 1977 (Industrial Application)).

In addition, **div 14** of the Patents Act 1977 provides that:

- the specification of an application for a patent must disclose the invention in a manner which is clear enough and complete enough for it to be performed by a person skilled in the art (**s14(3)** Patents Act 1977 (insufficiency)); and
- the claim or claims of an application for a patent must be supported by the description (**s14(5)(c)** Patents Act 1977 (lack of support)).

Each of these five requirements for the grant of a patent are relevant to the issue of plausibility. Further the first four of these requirements are also grounds for revocation of the granted patent; see **s72(1)(a)** Patents Act 1977 (patentable invention) and **72(1)(c)** Patents Act 1977 (insufficiency).

Further, plausibility has also been raised in the context of priority (**s5** Patents Act 1977). Priority is not itself a ground for refusal of an application for a patent or a ground of revocation of a granted patent of revocation of a granted patent, but the consequence of losing priority may lead to another ground for refusal or of revocation (i.e. intervening prior art for the purposes of novelty and inventive step).

5. Under the case law or judicial or administrative practice in your jurisdiction, are there decisions or rules that specifically apply to plausibility? If yes, please briefly explain

Yes

Please Explain
The key cases are as follows:

In relation to the law of the EPO:

- **T1329/04 Johns Hopkins** established that when considering inventive step, the specification must make it plausible that the claimed invention solves the technical problem put forward by the patentee. If the specification does not make the solution plausible, then that technical problem cannot be relied upon when considering inventive step. A new (likely less ambitious) problem that can be solved by substantially all of the claimed compounds must instead be advanced. The EPO’s Technical Board of Appeal (or “TBA”) did not give any detailed explanation of what is required for something to be made plausible. It is clear from the decision that, at least, some information must be provided in the patent which goes "beyond speculation".

- **T609/02 Salk** established that when considering sufficiency where a claim includes the functional technical feature that a claimed compound is useful for some therapeutic purpose, then the patent specification must provide some information reflecting the therapeutic application e.g. indicating that the claimed compound has a direct effect on a metabolic mechanism specifically involved in the disease. In that case the EPO did not set out an absolute rule demanding that particular information must always be included in a patent application to establish plausibility in every case (for example, particular types of experimental data). Instead, it adopted a less rigid approach. The Technical Board of Appeal noted that the plausibility threshold requires different amounts of information, depending on the nature of the invention and the surrounding common general knowledge in each case. It is clear from the TBA’s decision that it is not necessary to provide absolute proof of an effect in the patent specification but equally a simple verbal statement in a patent specification that compound X may be used to treat disease Y will not be sufficient.

In relation to UK law:

- The cases have broadly followed the principles established in the EPO case law discussed above. We have set out the core cases of the UK’s higher courts (Court of Appeal and Supreme Court) on plausibility below. We address further cases that deal with plausibility in question 6.

- In relation to inventive step, the Court of Appeal in **Generics [UK] Limited t/a Mylan v Yeda Research and Development Co. Ltd and another [2013] EWCA Civ 925** noted at paragraph 49(v) that "a technical effect which is not rendered plausible by the patent specification may not be taken into account in assessing inventive step", adopting the approach of the EPO in **Johns Hopkins**.

- In relation to sufficiency, the Court of Appeal in **Regeneron v Genentech [2013] EWCA Civ 93**, which referred to the TBA’s decision in **Salk**, held in paragraphs 100 and 101 that it must be possible for the skilled person to make a reasonable prediction that the invention will work with substantially everything falling within the scope of the claim, which the Court specifically equated with the requirement that "the assertion that the invention will work across the scope of the claim must be plausible or credible ". The Court of Appeal went on to state that if such a prediction could not be made (in other words, if the assertion were not plausible) then the scope of the patent monopoly would exceed the patentee's technical contribution to the art, thus rendering the claim insufficient.

More recently the Supreme Court in **Generics v Warner-Lambert** endorsed the EPO's approach in **Salk** (and arguably went further by requiring the patent to demonstrate in every case a direct effect on a metabolic mechanism specifically involved in the disease). The majority judgment stated at paragraph 35 that:

- "the patentee cannot claim a monopoly of a new use for an existing compound unless he not only makes but discloses a contribution to the art... the disclosure in the patent must demonstrate in the light of the common general knowledge at the priority date that the claimed therapeutic effect is plausible".

And in paragraph 37:

“Fourth, although the disclosure need not definitively prove the assertion that the product works for the designated purpose, there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true. Fifth, that reasonable prospect must be based on what the TBA in SALK (para 9) called "a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se."
The majority judgment of the Supreme Court made clear that the requirement that the effect of a drug is made plausible must be more than merely showing that it is positively possible that that drug would be effective as opposed to “not impossible”. To this end, the judgment noted in paragraph 52 that “everything is possible that is not impossible, but “not impossible” is very far from being an acceptable test for sufficiency. Plausibility may be easy to demonstrate, but it calls for more than that.”

The English courts have tended to consider the plausibility requirement, and the approach to its assessment, as being the same whether raised in the context of sufficiency or inventive step. This was confirmed by the Court of Appeal in *Idenix v Gilead* [2016] EWCA Civ 1089 at paragraph 114.

The Supreme Court also considered plausibility in the context of industrial application in the case of *Human Genome Sciences Inc v Eli Lilly & Co* [2011] UKSC 51. In light of the recent development of the concept of plausibility in the context of inventive step and sufficiency, it seems likely that plausibility will feature more frequently in relation to those grounds of invalidity rather than industrial application. However, the principle on plausibility stemming from this case is the same, summarised in paragraph 107 as being that a merely “speculative” proposed use of a claimed substance will not suffice, so “a vague and speculative indication of possible objectives that might or might not be achievable” will not do.

In relation to lack of support of the claim, the absence of any tests or experiments in support of claims for a new use of a known drug will normally result in the claim being refused on the basis that it is not supported by the description; see *Prendergast’s Applications* [2000] RPC 446 (Neuberger J).

Please briefly describe the general patentability requirements under the case law or judicial or administrative practice of your jurisdiction that are or would be relevant to the issue of plausibility. If there is no explicit or implied plausibility requirement in the law or under the judicial or administrative practice in your jurisdiction, please skip the below questions and proceed directly to question 15.

**Inventive Step and Sufficiency:** Plausibility has most frequently been raised in the context of the patentability requirements of inventive step and sufficiency. For example, in addition to the cases mentioned in question 5 above the English High Court has addressed plausibility in the context of sufficiency and/or inventive step in the following cases:

- *Eli Lilly v Genentech* [2019] EWHC 387 (sufficiency) which was the first case in which the High Court applied the decision of the Supreme Court in *Warner-Lambert* in relation to plausibility;
- *Merck v Shionogi* [2016] EWHC 2989 (sufficiency) in which it was held in paragraph 185 that plausibility in the context of inventive step is not limited to compound claims, but can also be raised in relation to claims including a functional limitation;
- *GSK v Wyeth* [2016] EWHC 1045 (Ch) (inventive step and sufficiency);
- *Accord v Medac* [2016] EWHC 24 (Pat) (sufficiency) in which it was held in paragraph 129 that the identity of the patentee (in that case found to be a well-respected pharmaceutical company) was not a factor which could be taken into account when considering the plausibility of the alleged technical contribution disclosed in the patent;
- *Merck v Ono* [2015] EWHC 2973 (Pat) (inventive step);
- *Actavis v Eli Lilly* [2015] EWHC 3294 (inventive step and sufficiency) in which it was held at paragraph 175 that plausibility does not apply only to claims of wide scope, although as a matter of fact it may be easier to demonstrate plausibility for narrow claims than for wide claims. This was an extreme case where the patent contained no more data than the prior art but the invention was found both inventive and plausible;
- *Hospira v Genentech* [2014] EWHC 1094 (Pat) (sufficiency);
- *Eli Lilly v Janssen* [2013] EWHC 1737 (sufficiency); and

**Industrial Application:** As noted above in question 5, plausibility has also been considered in relation to industrial application (however, we consider that this ground will play a smaller role in the future.

**Novelty and Priority:** In addition, plausibility has been found to be relevant to anticipation (in, for example, *Merck v Ono* [2015] EWHC 2973 (Pat) and *Actavis v ICOS* [2017] EWCA Civ 1671) and priority (in *Hospira v Genentech* [2014] EWHC 1094 (Pat) – contrary to the
approach of the EPO in T903/05 *Gemvax* – as well as *Actavis v Lilly* [2015] EWHC 3294 (Pat) and *Actavis v ICOS* [2017] EWCA Civ 1671. This is because of the role of enabling disclosure in relation to both of these concepts. For example, in the context of anticipation a piece of prior art must not only disclose the claimed invention but must also provide enough information to enable the skilled person to carry out the disclosure which would anticipate the invention. This clearly has close parallels to the law on sufficiency.

**Lack of support of the claim:** In relation to an application for a patent, plausibility has been found relevant when considering s14(5)(c) of the Patents Act 1977 which provides that the claim or claims of an application must be supported by the description. In particular, in *Prendergast’s Applications* [2000] RPC 446, it was held by the Patents Court (Neuberger J) that the absence of any tests or experiments in support of claims for a new use of a known drug meant that the claims were not supported by the description. See also the judgment of Aldous J in *McManus’s Application* [1994] FSR 558 upholding the decision of the UK Patent Office to the same effect.

### Question

7. **Can the plausibility requirement be regarded primarily as a “credibility” requirement, i.e., a requirement applying to patent applications that describe a technical effect that appears non-credible, e.g., because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?**

**Yes**

Please Explain

The plausibility requirement can be regarded as a credibility requirement in a general sense, but not exclusively. The requirement will apply to all patent applications – it is not limited in its application to patents which are shown to contradict the general expectations in the field and/or describe a surprising effect. If the question is suggesting that the plausibility requirement only applies where the technical effect suggested in the patent is non-credible or inherently implausible, then it is noted that this proposition was rejected by Lord Sumption in the Supreme Court decision of *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan)* [2018] UKSC 56 at [30].

7.a **If yes, is the credibility determined from the perspective of a person having ordinary skill in the art, or from the perspective of an expert in the field?**

**No**

Please Explain

This not a ‘yes’ or ‘no’ question.

The credibility of the technical contribution said to be made by an invention is determined from the perspective of a person having ordinary skill in the art. See, e.g., Lord Sumption in *Warner-Lambert v Generics* at [37]: “there must be something that would cause the skilled person to think that there was a reasonable prospect that the assertion would prove to be true” and "it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent" and at [48]: “The question, it must be remembered, is not whether it is plausible but whether the specification discloses something that would make it so in the eyes of the skilled person”.

7.b **If the relevant perspective is the person having ordinary skill in the art, why is a “credible” technical effect not also obvious at the same time?**

**No**

Please Explain

There is no ‘yes’ or ‘no’ answer to this question.

The assessment of inventive step is conducted through the eyes of the skilled person at the priority date **without** knowledge of the patent, whereas the assessment of “credibility” (in the context of plausibility) is conducted **with** knowledge of the patent. However the standard to be met in each case is the same – see Lord Sumption in *Warner-Lambert v Generics* at [37]:
“The disclosure of those grounds marks the difference between a speculation and a contribution to the art. This is in substance what the Technical Board of Appeal has held in the context of article 56, when addressing the sufficiency of disclosure made in support of claims extending beyond the teaching of the patent. In my opinion, there is no reason to apply a lower standard of plausibility when the sufficiency of disclosure arises in the context of EPC articles 83 and 84 and their analogues in div 14 of the Patents Act. In both contexts, the test has the same purpose.”

It is therefore possible for a patent to be insufficient for lack of plausibility but inventive at the same time (at least in relation to “classic” obviousness under UK law, e.g. Generics v Warner-Lambert) because the patent contains some new information which is not obvious from the prior art but not enough to make the patent plausible. It is also possible for a technical effect to be “credible” and inventive at the same time (e.g. Actavis v Eli Lilly [2015] EWHC 3294). As a result, in the UK, parties will often introduce a so-called “squeeze” between obviousness and plausibility to put pressure on a patentee in navigating the line between obviousness and sufficiency.

7.c
Do all the promises of the patent description have to seem achievable for the person skilled in the art?

No

Please Explain

Only the technical contribution upon which the patentee relies needs to be made plausible by the disclosure of the specification. For sufficiency, this will be determined by the functional features written into the claim. For inventive step, the technical contribution to be made plausible will be whatever non-obvious technical contribution the patentee says is made by the claimed invention.

8
Can the plausibility requirement be regarded primarily as a prohibition of “speculative” patent applications which do not (expressly) disclose a technical effect or concrete use, e.g., of a chemical substance (the potential technical effect or concrete use rather remains speculative)?

Yes

Please Explain

Yes, but not exclusively.

The UK Courts have stated on several occasions that the requirement of plausibility is designed to prohibit speculative claiming and aims to ensure that the patent bargain is met. The UK Courts consider speculative applications are those in which the technical effect is based on mere assertion i.e. where there is no teaching in the patent which provides a real reason to suppose the promised technical effect is true. The Court of Appeal put it as follows “[the requirement of plausibility] is designed to prohibit speculative claiming, which would otherwise allow the armchair inventor a monopoly over a field of endeavour to which he has made no contribution”. However, the Supreme Court noted in Generics v Warner-Lambert that speculative claiming is simply one way in which a patentee may attempt to extend its monopoly beyond what was contributed to the art, another way would be, for example, by claiming a wider monopoly than is supported by the disclosure in the patent (i.e. by overbroad claims).

8.a
If yes, which standard does apply to determine a speculative filing? Which requirements does the applicant have to meet in order to reach a non-speculative filing?

The test for plausibility, be it in the context of sufficiency, inventive step, priority and industrial applicability, is the test that is used to determine a speculative filing. The Courts have made clear that plausibility is a threshold test. The Supreme Court stated in Warner Lambert, in the context of sufficiency, that “the test is relatively undemanding” (although the UK Group considers that threshold is the same irrespective of the context in which plausibility arises).

When considering whether a technical effect is plausible in the light of the teaching of the specification what must be shown is “a real reason for supposing that the claimed invention will indeed have the promised technical effect” (as per the Court of Appeal in Idenix and echoed by the Supreme Court in Warner-Lambert at paragraph 36 and 37).

Further, sufficiency is a characteristic of the disclosure of the patent. As held by the Supreme Court in Generics v Warner-Lambert “sufficiency is a characteristic of the disclosure, and these matters must appear from the patent. The disclosure may be
supplemented or explained by the common general knowledge of the skilled person. But it is not enough that the patentee can prove that the product can reasonably be expected to work in the designated use, if the skilled person would not derive this from the teaching of the patent. Therefore, there must be some disclosure/information in the specification itself which renders the technical effect plausible.

3. If a technical effect (which is not expressly described in the specification) is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification, why was the technical effect not obvious at the priority date?

As discussed above, a key point which must be kept in mind is that for the assessment of plausibility the skilled person is considering the disclosure of the patent specification itself. For obviousness, the skilled person is considering the state of the art without knowledge of the patent. There may, therefore, be circumstances where a technical effect is plausible as it is self-evident from the specification and yet the technical effect is not obvious but this will depend on the specific facts of the case (e.g. Actavis v Eli Lilly). It should be noted, however, that there must be disclosure in the specification which makes the technical effect plausible and, whilst this disclosure can be supplemented by the common general knowledge, it cannot be replaced by it.

9. Can the plausibility requirement be regarded primarily as specific prohibition against "prophetic" examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g., the description merely "predicts" that a specific experiment "will" prove a special property of the claimed compound?

No

Please Explain

No. Prophetic examples may be relevant to the assessment of plausibility (as more generally described in the response to questions 7 and 8 above). Thus it is not necessary to have data in support of a claimed invention and a priori reasoning may be sufficient. As Lord Sumption explained in [37] of Generics v Warner-Lambert:

“Plausibility is not a term of art, and its content is inevitably influenced by the legal context. In the present context, the following points should be made […] Fifth, that reasonable prospect must be based on what the TBA in SALK (para 9) called “a direct effect on a metabolic mechanism specifically involved in the disease, this mechanism being either known from the prior art or demonstrated in the patent per se.” Sixth, in SALK, this point was made in the context of experimental data. But the effect on the disease process need not necessarily be demonstrated by experimental data. It can be demonstrated by a priori reasoning. For example, and it is no more than an example, the specification may point to some property of the product which would lead the skilled person to expect that it might well produce the claimed therapeutic effect; or to some unifying principle that relates the product or the proposed use to something else which would suggest as much to the skilled person.”

On the facts of Warner-Lambert however a priori reasoning was not enough. As explained at [53], the patent contained reference to two well-known models for peripheral neuropathy, but no data were presented from either model. Nor did the specification comprise any information to link the data in the patent from models relevant to other indications, to the claimed indication. In that instance the identification of the two models in the patent, alongside expert evidence that the skilled person would be encouraged by the data in the patent to carry out those tests on the drug which was the subject of the patent, was not, alone, enough to render the patent plausible.

“In classical insufficiency cases, where the question is whether the disclosure in the patent enables the skilled person to perform the invention, the skilled person may be assumed to supplement the disclosure by carrying out simple tests. In cases like this one, where the invention is novel but the objection of insufficiency is that the claim exceeds the disclosed contribution to the art, the role of hypothetical “simple tests” is necessarily more limited. As the EPO Technical Board of Appeal observed in JOHNS HOPKINS, at para 12, the specification can be said to contribute to the art if it solves a problem, but not if it merely poses one. Or as Lord Hoffmann observed in a passage that I have already quoted, the notion that something is “worth trying” cannot be enough without more to justify a monopoly. The specification in the present case says nothing about neuropathic pain of any kind. It says nothing about central sensitisation, which is said to provide a link between neuropathic and inflammatory pain. The mere fact that the skilled team, faced with an apparent discrepancy between the breadth of the claims and the absence of supporting data in the specification, would be encouraged to fill the gap by carrying out tests of its own, serves only to confirm the absence of any disclosed contribution to the art.”
9.a If yes, which standard does apply to identify a prophetic example? Must the applicant submit test data etc. to support examples (unless self-evident)?

Not applicable.

9.b Do all examples (or embodiments) need to pass this plausibility test? What is the consequence if only some examples (or embodiments) do not pass the test?

No

Please Explain

The focus is on whether the technical contribution that the patentee relies on passes the test. If the technical contribution can fairly be said to be made plausible in the examples or embodiments, that should be enough.

10 Is it possible to make a clear distinction between the above-mentioned aspects (as set out in the questions 7-9 above) or do they merge into each another?

No

Please Explain

The above-mentioned aspects (as set out in questions 7-9 above) merge into one another; it is not possible to make a clear distinction between them.

11 What is the relevant point in time for the plausibility test?

The priority date (or the filing date, if not relying on priority filings) of the patent, through the eyes of the skilled person.

What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?

If it can later be proved that the technical effect does not exist, then the patent may be invalidated on that basis but that is a separate consideration to plausibility. If a patent fails to make a technical effect plausible, the patentee cannot rely on subsequent information demonstrating that in fact the claimed subject matter achieves that technical effect to overcome the lack of plausibility (we do not address the use of post-priority data in this question).

12 Are there different plausibility tests for different types of claims (e.g. pure product/compound claims without a functional feature, product claims including a functional feature, second medical use claims, etc.)?

No

Please Explain

No. However, as Lord Sumption said in the Supreme Court decision of Generics v Warner-Lambert at [37]: “Plausibility is not a term of art, and its content is inevitably influenced by the legal context.”
"In that case, the claims at issue were Swiss-form second medical use claims. This was most recently confirmed by Mr Justice Arnold in the High Court’s decision in Eli Lilly v Genentech [2019] EWHC 387 (Pat) who held at [531] that the test set out in Warner-Lambert also applied to other types of claims: “In my judgment, I am bound by the law as stated in Warner-Lambert. As Lord Sumption acknowledged, the application of the requirement of plausibility depends on context. I accept that, in applying the principles laid down by Warner-Lambert to the facts of present case, it is necessary to take into account the fact that the Patent concerns a new (at least in the sense of being newly found to exist in humans) member of a known family. I do not accept that this requires any modification of those principles, if that is what counsel for Genentech was suggesting.” This is consistent with the fact that plausibility has developed as a means of preventing speculative patent filings generally.

Therefore, although the legal principles of plausibility are constant, what is or is not “plausible” will be highly fact specific.

13 Who has the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?

Where the Examiner raises an objection to an application for a patent based on lack of plausibility, it is for the applicant to satisfy the Examiner that the invention is plausible, notwithstanding the Examiner’s objection.

After grant, a patent is prima facie valid under English law and the burden of proof for establishing its invalidity for lack of plausibility (or for any other ground) falls on the party alleging that the patent is invalid. However, under English law, where the party alleging invalidly adduces evidence that establishes a prima facie case that the invention is implausible, then the burden of proof will shift to the patent proprietor to show that the invention is in fact plausible.

The evidence required to establish a prima facie case that the invention is implausible will be likely to vary from case to case and will depend on all the circumstances, including the nature of the invention and the experimental tests and data (if any) disclosed in the specification to support the plausibility of the invention. However, by way of example, where no experimental tests or data are disclosed in the specification to support a claim for a new therapeutic use of a known pharmaceutical product, the court may readily conclude that a prima facie case that the patent is invalid for lack of plausibility has been made out and that, consequently, the burden of proof shifts to the patent proprietor to show that the invention is in fact plausible.

14 Please comment on any additional issues concerning any aspect of plausibility that is being regulated by your Group’s law/practice you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.

Not applicable.

II. Policy considerations and proposals for improvements of your Group's current law

15 Are there aspects of your Group’s current law relating to plausibility that could be improved? If YES, please explain.

Yes

Please Explain

The UK Group believes that the law relating to plausibility is an effective tool to ensure that the so-called patent bargain is protected (i.e. that a monopoly is obtained in return for disclosing the invention and dedicating it to the public for use after the monopoly has expired) and that the monopoly corresponds to the technical contribution of the patentee. However, the law on the issue is arguably imperfect. While its origins stem from the EPO decisions in AgrEvo (T939/92) and Johns Hopkins (T1329/04), in recent years the UK law has expanded from the EPO’s original jurisprudence, albeit arguably consistently with the ratio in Salk. The key decisions in the UK relate not only to inventive step (the main original focus of plausibility at the EPO), but also to insufficiency, priority, industrial applicability and potentially even novelty. It is this development, along with an absence of an explicit provision in the legislation that has caused concern by some parties in some sectors. A particular practical concern is that the standard has been developed by case law after some patents were filed 20 years ago. This may create difficulties for those patents given that current legal standards are retrospectively applied to existing patents.

While there are Supreme Court decisions on plausibility, there remains the possibility of a lack of uniform application. Exactly which patents require data in the specification (as opposed to a reasoned explanation of scientific theory) and what type of data is sufficient...
In any event, there is doubt as to whether such a factor should have as much weight when extrapolated to other grounds, i.e., inventive step under TRIPS which requires all inventions to be treated equally. However, it is not clear that this different approach to different types of invention is fair, or compliant with TRIPS.

In contrast, inventions such as a new dosage for a drug are likely to be subject to a requirement for more concrete evidence of plausibility. For example, Lord Neuberger set out that for a patent disclosing a new protein and its encoding gene, a plausible or reasonably credible claimed use or an educated guess of a use can suffice for demonstrating industrial applicability.

Like all case law, the assessment of plausibility varies on the facts of each case and the context in which plausibility arises. It can be fairly said that plausibility particularly affects the heavily regulated life sciences sector. Pharma companies have to constantly tackle the dilemma of whether to file a patent application early and risk facing an allegation that the invention was not plausible at that earlier stage, or delay filing until further costly and time-consuming clinical trials are conducted. Waiting until this later stage increases the risk of losing out on patent protection as a result of intervening prior art, particularly given any requirements to make the carrying out of the clinical trial and the subsequent data public.

Judges in the UK are conscious of the need to ensure that patent protection is available in order to incentivise inventions in the pharmaceutical sector. There is thus a balance that needs to be struck between "early" disclosure (which risks incomplete disclosure) and "complete" disclosure (which risks invalidation by intervening prior art). This, is therefore, a delicate balance. Failure to apply a consistent international standard is likely to result in good inventions being unable to obtain consistent protection in a global market: filings that meet low hurdles may act as prior art to, and jeopardise, filings in countries with higher hurdles. Hurdles that change over time are likely to render invalid protection on which inventors might previously have relied on for investment.

The Supreme Court takes seriously the views held by industry when it comes to the issue of plausibility. For example, it granted permission to the UK Bioindustry Association (BIA) to intervene in its review of Warner-Lambert Company LLC v Generics (UK) Ltd [t/a Mylan] [2018] UKSC 56 and Actavis v Eli Lilly [2015] EWHC 3294, and appears to have attached weight to their views, so that it could fully understand the impact of the amount of data and evidence required before an invention can be patented vis-à-vis the issue of "plausibility" in patent law.

b. Case by case basis

Like all case law, the assessment of plausibility varies on the facts of each case and the context in which plausibility arises.

A fundamental invention which opens a new field of research and development appears more likely to be considered plausible despite being disclosed at an early stage than would be the case for the more incremental inventions. For example, in Human Genome Sciences Inc v Eli Lilly & Co [2011] UKSC 51, plausibility arose when tackling the question of whether particular biological material had industrial applicability. Lord Neuberger set out that for a patent disclosing a new protein and its encoding gene, a plausible or reasonably credible claimed use or an educated guess of a use can suffice for demonstrating industrial applicability.

In contrast, inventions such as a new dosage for a drug are likely to be subject to a requirement for more concrete evidence of plausibility such as data from clinical studies. However, it is not clear that this different approach to different types of invention is fair, or compliant with TRIPS.

In any event, there is doubt as to whether such a factor should have as much weight when extrapolated to other grounds, i.e., inventive step...
III. Proposals for harmonization

Please consult with relevant in-house / industry members of your Group in responding to Part III.

17 Under your Group’s current law, does the plausibility requirement, if any, interfere with the incentive for an early disclosure provided by the first-to-file system?

Yes

Please Explain

No matter how low the plausibility threshold is, the mere fact that there is a plausibility requirement means that the patentee will have to consider carefully whether or not it has sufficient evidence to justify a filing.

Whilst patent applications can be supplemented with further evidence within a year of filing there is still a clock running i.e. the clock the patentee started upon filing the patent application. If the plausibility requirement is not met, patent protection may be lost because of the details that are published.

The reality is that in the pharmaceutical sector no company files in just one territory. The patent filing programmes are international in scope. A company must therefore determine which country, in which the company has a commercial interest and seeks patent protection, has the highest plausibility requirement. This will then set the bar for the evidence the company needs to gather in advance of any patent application it makes.

The system should above all aim for a consistent international plausibility threshold; only then would there be no interference with the incentive for early disclosure.

18 Do you consider that harmonization regarding plausibility is desirable? If YES, please respond to the following questions without regard to your Group’s current law. Even if NO, please address the following questions to the extent your Group considers your Group’s current law could be improved.

Yes

Please Explain

19 Should there be a plausibility requirement? If no, please briefly explain why and then please also answer the following questions assuming there is a plausibility requirement.

Yes

Please Explain

and sufficiency – where the touchstone is and should be whether the technical contribution is made plausible.

c. A dichotomy

The above question makes an attempt to separate out “early disclosure” of technical achievements and disclosure of “completed” inventions. As the above discussion suggests, UK law does not recognise any such dichotomy. The point of early disclosure in the UK is that one is always required to make a complete disclosure, but the standard for assessing what is complete will vary depending on the nature of the invention.
### Question 20

**Should plausibility be a “credibility” requirement that excludes patent applications describing a technical effect of the claimed invention which however looks “incredible”, e.g. because the described effect contradicts the common perception of in the relevant technical field, and/or is a surprising effect?**

**Yes**

Please Explain

Yes (amongst other things) (in answering this questions we have assumed that “credibility” has not imported a higher standard than that already provided for by the concept of “plausibility”).

### Question 20.a

**If yes, which standard should apply to determine the credibility of the invention? Is the credibility determined from the perspective of a person having ordinary skills in the art, or from the perspective of an expert in the field?**

The standard to be applied to determine the credibility of the invention should: (i) be a pre-condition to validity, (ii) represent a low threshold to overcome, (iii) be narrowly understood, and (iv) be relatively undemanding. Thus, the threshold should be met if, e.g., the specification provides an educated prediction based on a reasonably credible theory or a priori reasoning; (i) as to why the invention will work, or (ii) which enables the skilled person to test the invention (without undue burden). On the flip side, a mere theoretical or purely hypothetical assumption or bare assertion, without a theoretical or reasoned basis, should not be enough to satisfy the credibility threshold. The credibility should be determined from the perspective of the skilled person.

### Question 20.b

**Should all the promises of the patent description have to seem achievable for the person skilled in the art?**

**No**

Please Explain

Only the technical contribution upon which the patentee relies as protected by the claims of the patent needs to be made plausible by the disclosure of the specification. For sufficiency, this will be determined by the functional features written into the claim. For inventive step, the technical contribution to be made plausible will be whatever non-obvious technical contribution the patentee says is made by the claimed invention.

### Question 21

**Should plausibility be a prohibition of “speculative” patent applications which do not (expressly) disclose a technical effect or concrete use e.g. of a chemical substance (the potential technical effect or concrete use rather remains speculative)?**

**Yes**

Please Explain

Yes (amongst other things).

There is a need to ensure that the scope of a patent monopoly does not exceed the patentee's technical contribution to the art and that the patent bargain is met by the patentee. A requirement for plausibility has a role within this context to ensure that there has been a sufficient technical contribution to warrant the grant of a monopoly right.

### Question 21.a

**If yes, which standard should apply to determine a speculative filing? Which requirements should the applicant have to meet in order to reach a non-speculative filing?**

The standard should be set so as to ensure that the patentee has made a contribution to the art commensurate with the scope of the patent. The patent application ought to provide a basis for the skilled person, with his or her common general knowledge, to
establish that the patentee has, in fact, made a technical contribution for which protection is claimed. In addition, the scope of the claims of the patent need to be in line with the technical contribution and should not be broader than the advance made by the patentee.

The standard to be applied should be one of making the technical effect plausible (i.e. seeming reasonable or probable) to the skilled person rather than the patentee being required to prove or demonstrate the technical effect. Accordingly, there ought to be no absolute requirement for experimental results/data in a patent application. The situation for each patent will be different and therefore it is difficult to give a more specific test.

One indicium of the speculative nature of an invention is the inclusion of long lists of widely varied alternatives, especially if some are contradictory or non-operative. The presence of such lists in a patent should be taken into account and treated as a factor that tends to suggest that the patent is making speculative claims. Such an inference may be countermanded in relation to specific items in the list by appropriate specific information.

**18** What should be the consequence if a technical effect which is not expressly described in the specification is nonetheless plausible because the skilled person would understand that the technical effect was, at the priority date, implied or self-evident from the specification?

The absence of evidence, or verifiable facts, in the application should not matter if the common general knowledge makes the disclosure/technical effect of the patent plausible. The result of the technical effect being only plausible from the skilled person’s common general knowledge may impact the assessment of validity of the patent under other grounds (such as inventive step). However, if the technical effect is plausible, be that through the disclosure in the specification or from the disclosure and the skilled person’s common general knowledge, this should be sufficient to overcome an objection of lack of plausibility.

**22** Should plausibility be a specific prohibition to refer to “prophetic” examples (or embodiments) in the specification in support of the technical solution purported by the claimed invention, e.g. the description “predicts” that a specific experiment “will” prove a special property of the claimed compound?

No

Please Explain

Not applicable

**23** Should all examples (or embodiments) need to pass this plausibility test? What should be the consequence if only some examples (or embodiments) do not pass the test?

No

Please Explain

Not applicable

**24** What should be the relevant point in time for the plausibility test? What if for example the technical effect of an invention appears plausible at the priority date, but later proves to be wrong, or vice versa?
The priority date of the patent should be the relevant point in time. This is consistent with treating plausibility as an aspect of well-recognised validity criteria such as inventive step or sufficiency of disclosure.

Where a plausibility challenge arises in the context of sufficiency, lack of inventive step or industrial applicability, the evidence which may be used to support or challenge the plausibility of a claimed invention should be limited to information contained in the application/patent itself read in conjunction with the 'common general knowledge' of the skilled person at that date. Thus, the patent must itself provide the basis for the plausibility and that basis must be such that the skilled person would have recognised the plausibility of the proposition at the priority date using only their common general knowledge. Potentially the information in the patent could be supplemented by information contained in documents expressly cited in the application/patent in question, depending on the status of such documents generally in the country in question.

If an invention is not plausible on this basis, it should not be open to the applicant/patentee to adduce other data or evidence to make it so. If permitted, then this would undermine the aim of guarding against speculative claims. Equally, evidence from a challenging party or patent granting authority should be limited to the common general knowledge interpretation of what is disclosed in the patent.

If information arises after the priority date which would, if it had been available at the priority date, have caused the patent to lack plausibility, then such information should be usable by a challenger to argue that the claim is insufficient (e.g. that the invention is not enabled or lacks inventive step), but not to support an argument that it lacks plausibility; the plausibility of the patent at the priority date remains unaffected.

Where plausibility is raised in the context of novelty, the same applies except that the assessment of plausibility should be performed in the absence of the information contained in the patent – instead it should be based on the prior art together with the skilled person's common general knowledge.

Similarly, in the context of assessing priority (i.e. whether the claimed invention is supported by the disclosure of the priority document), the assessment of plausibility should be performed based on the information in the priority document together with the skilled person's common general knowledge.

### Question 24

**Should there be different plausibility tests for different types of claims (e.g. pure product/compound claims without functional feature, product claims including functional feature, second medical use claims, etc.)?**

No

**Please Explain**

The same legal principles should be applied in each case, albeit that the outcome will depend on the facts of each case, including the nature of the invention claimed and the state of the relevant common general knowledge.

### Question 25

**Who should have the burden of proof for (lack of) plausibility (patentee/applicant or patent office/opponent)?**

See the response to Question 13. The shifting burden of proof works well in practice and enables the court to meet the justice of the case whatever the particular circumstances.

### Question 26

**Please comment on any additional issues concerning any aspect of plausibility you consider relevant to this Study Question, having regard to the scope of this Study Question as set out above.**

Further to paragraph 24, the same standard of plausibility should be applied for different grounds of invalidity (e.g., be it inventive step, sufficiency or priority).

### Question 27

**Please indicate which industry sector views provided by in-house counsel are included in your Group’s answers to Part III.**
Life sciences, but also telecoms and manufacturing.