Current Patenting Issues in Europe Facing Life Sciences/Biotech Innovators and Effective Claim Drafting Strategies to Avoid Pitfalls

This paper was originally submitted to the American Intellectual Property Law Association (AIPLA) ahead of its 2021 Annual Meeting and was the subject of a presentation at a plenary session there on 28 October 2021. The author, Andrew Bentham, is a partner in the Biotechnology and Life Sciences group of J A Kemp LLP (Cambridge, UK). If you wish to discuss any of the issues covered in the paper, please feel free to contact Andy by email (abentham@jakemp.com).

This paper is in two sections. The first relates to current topics, issues and developments in European patent practice in that may be relevant for innovators in the life sciences. As far as possible, this first part tracks the issues discussed from a US perspective in the paper submitted by my co-panellist Courtenay Brinckerhoff of Foley & Lardner LLP, in the hope that US-based readers can better compare the situation in the US with that in Europe. The second part, focussing on differences between US and European practice and how to avoid these differences becoming pitfalls for US applicants, is more timeless – as in general these issues change relatively little over time, and yet they remain problems if they remain unfamiliar. For completeness, both sections include some information on issues that are general to all applicants but equally or especially relevant to those in the life sciences.

I. Current patenting issues in Europe facing Life Science innovators

A. Patent-eligibility

Patent-eligibility has of course been a very significant issue in US practice in the near-decade since the US Supreme Court decided the *Prometheus* case and opened up many questions that are still being worked out through follow-on case law today. Patent-eligibility has also been a significant issue in Europe since the European Patent Convention (EPC) first came into force in 1978. In part because of the drafting of the EPC and in part because of the rapid changes in life science technology since it was implemented, much of this debate has tended to focus on the metes and bounds of various exceptions to patentability in the life sciences.

However, the contours of these issues are at present very different. This may be because, while US law on eligibility is generally judge-made case law, the EPC has a

hardwired black-letter framework of exceptions to patentability[1]. In the life sciences, these include prohibitions on patenting, for example, methods of medical treatment (Art 53(c) EPC) and plant varieties (Art 53(b)), which do not arise in US law. Similarly, the EPC's "morality" exclusion (Art 53(a)) has in practice been a life science issue as questions came to be asked about patenting subject matter such as human genes, transgenic plants and human embryonic stem cells.

This highlights an issue. The EPC came into force in the 1970s but the thinking underlying it goes back even further, to a time when much of what we today call biotechnology was at best science fiction. The Articles of the EPC, which can only be changed via agreement of all the (now 38) member states have been amended hardly at all since then and only fairly limited codification[2] via rules amendments has been possible. The EPC is therefore by its nature somewhat inflexible on patent-eligibility. This contrasts with the situation in the USA where 35 USC §101 is very general and case law fills the gaps. The US Supreme Court has therefore at various times taken what are in effect policy decisions on the eligibility of certain subject matter.

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[1] See Articles 52 and 53 EPC

Article 52- Patentable inventions
(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.
(2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
(a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information.
(3) Paragraph 2 shall exclude the patentability of the subject-matter or activities referred to therein only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Article 53 - Exceptions to patentability
European patents shall not be granted in respect of:
(a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;
(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;
(c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.

[2] See Rules 28 and 29 EPC

Rule 28 - Exceptions to patentability
(1) Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:
(a) processes for cloning human beings; (b) processes for modifying the germ line genetic identity of human beings; (c) uses of human embryos for industrial or commercial purposes; (d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.
(2) Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process.

Rule 29 - The human body and its elements
(1) The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.
(2) An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.
(3) The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

This is not to say that case law has not played a critical role in development of practice on patent-eligibility in Europe too. Every one of the exceptions in the EPC has been the subject of case law developed as applicants tried to maximise what they could claim notwithstanding the exceptions, and much of what we know about how to interpret them originates from decisions of the EPO's Enlarged Board of Appeal (EBA)[3], but even the EBA always has to operate within the more defined framework defined by the legislation. Sweeping changes such as those that began with *Prometheus* are therefore much harder to envisage.

Whether this is an advantage or a disadvantage for life science innovators may depend on exactly what field of life science one is concerned with. For example:-

- The EPC does exclude diagnostic methods from patent-eligibility but only those practised on the human or animal body, so methods performed on samples taken from patients are patent-eligible even without the specific technique steps that it sometimes helps to add in the USA.

- Under Rule 29(2) EPC, isolated genes are specifically stated to be patent-eligible even if their sequence is the same as a naturally occurring one; this also applies equally to human genes.
- Isolated microbial strains have always been patentable when claimed narrowly and supported by a biological deposit under the Budapest Treaty (see below) and are not especially encountering increased issues now.

In addition, there are areas where the EPC is *prima facie* unfavourable but in practice the exclusions have been mitigated by practice developments. The most important of these is of course methods of therapy, where inventions that relate to pharmaceuticals are little if any less protectable in Europe than in the USA. New active ingredients can be claimed as compounds *per se* (possibly more easily in some biopharma situations as antibodies, gene/ therapy vectors, cell therapies, microbial strains, products extracted from natural sources and so on would in practice face no scrutiny on eligibility grounds) and medical use claims[4] take care of many of the situations where methods of treatment would be claimed in the USA[5].

[3] Which, within the more limited context of patent law under the EPC, has a function somewhat similar to the US Supreme Court in that fundamental questions of law that arise are referred up to it and it returns answers to those questions that the regular Technical Boards use to decide the cases in front of them and that then exist as precedential case law for the future.
[4] Typically in the form "Compound X for use in the treatment of disease Y".
[5] Increasingly including finer details such as dosage regimens and sometimes patient groups, so these claim types now have a lot of power and flexibility.

On the other hand, some inventions are clearly patent-eligible in the USA and clearly patent-ineligible in Europe. An invention that is literally a method of treatment defined entirely by steps carried out by a physician on a patient will not be patent-eligible, and nor will a plant or animal variety[6] or breeding method (or, following recent EBA case law, the product of such a method[7]).

For most of the EPC's existence, US patent law has been more flexible and liberal on life science patent-eligibility; whereas currently the picture in Europe is relatively stable, and in some (but not all) ways more favourable. Put another way, patent-eligibility in life science has many times been a major issue in Europe but, right now, it is reassuringly more of a major non-issue compared to the USA.

B. Written description/enablement-type issues

In contrast, these topics are significant issues in Europe, but again the way the issues present themselves is not the same.

By way of background, written description under 35 USC §112 first paragraph is broadly analogous to support under Art 84[8] EPC and enablement under 35 USC §112 second paragraph is similar to sufficiency under Art 83[9] EPC. However, there are a few issues to be aware of:-

- In examination, Arts 83 and 84 are frequently elided by examiners so there is often little real distinction between the two; if the examiner believes there is not enough technical or data substance to back up the applicant's claims, both objections tend to be raised.

- In life sciences, support and sufficiency also blur with inventive step (Art 56[10] EPC), which is of course equivalent to obviousness under 35 USC §103 but can also be used to address what a US practitioner would probably think of as non-enablement or written description, in that part of the analysis is whether the applicant has actually solved the problem underlying the invention.

[6] Though it will likely be possible to obtain a plant variety right, similar to PVP in the USA.
[7] https://jakemp.com/en/knowledge-centre/briefings/european-plant-patent-eligibility-update-enlarged-board-of-appeal-decision-g319
[8] Article 84 – Claims: The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.
[9] Article 83 - Disclosure of the invention: The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.
[10] Article 56 - Inventive step: An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art. …

- Even leaving this aside, often the EPO is stricter on obviousness but less strict on enablement/written description than the USPTO. This is by no means an absolute phenomenon, more a rule of thumb, but it is notable that often applicants get similar claims issued in the two Offices by different routes. A particularly good example is that of claims to antibodies[11], where US law will typically require specification of the CDR or heavy/light chain variable region sequences to comply with 35 USC §112, whereas the EPO will more likely hold broader scope to anti-target antibodies in general obvious unless there is genuinely an invention in the identification of a new target[12] or the raising of an antibody to a known one, but either way the applicant ends up in a similar position.

- Arts 56 (inventive step) and 83 (sufficiency) are grounds for post-grant opposition in the EPO and revocation in national courts but Article 84 (support) is not. As the three overlap, this may not necessarily be decisive to the outcome of post-grant proceedings, but there are some cases where an attack that would have been strong under Art 84 is weaker[13] under Art 83, especially given that the burden of proof is on the opponent and the general standard for insufficiency one of "serious doubts substantiated by verifiable facts". The position is therefore somewhat pro-patentee in post-grant proceedings in the EPO[14]. Also, as most EPO Board of Appeal case law derives from oppositions, more cases are decided on Arts 56 and 83.

- More generally, although there are many such decided cases, these issues are as much a matter of practice than case law *per se*. There are occasional highlights but mostly each case turns on its facts such that there is to an extent a body of practice as opposed to a list of key decisions.

However, one such highlight is currently on the horizon, as a referral[15] is about to be made to the EBA on the so-called "plausibility" doctrine. Under the EPC, this arises as a matter of inventive step but (see above) it is akin to written description or enablement as the issue is the extent to which data not present in the application as filed but provided later on in examination by the applicant can be taken into account.

[11] https://jakemp.com/en/events/j-a-kemp-webinar-patenting-antibody-pharmaceuticals-at-the-epo https://jakemp.com/en/knowledge-centre/briefings/antibodies-in-the-european-patent-office-basic-principles https://jakemp.com/en/knowledge-centre/briefings/antibodies-in-the-european-patent-office-adanced-guide-to-drafting-and-prosecution

[12] But note that there is occasionally a genuine practice difference here too – although it is increasingly rare and hard to make out in practice as few new targets are identified these days, the EPO is still in principle open to what US case law used to accept as a "newly characterised antigen" test.

[13] For example because the real issue is not whether the skilled person could have put the invention into practice (sufficiency) but whether the claims are backed up by experimental material (support).

[14] Though not nationally in the UK, where the courts have become very hard on sufficiency in biotech cases.

[15] https://jakemp.com/en/news/enlarged-board-of-appeal-to-consider-the-doctrine-of-plausibility

The EPO's examination guidelines[16] endorse the use of such post-published data to evidence a technical effect associated with the claimed subject matter. Examination practice on this is maybe a little less liberal that in the USA, but is generally comparable as the submission of post-published data is widely taken into account.

However, case law has also introduced the principle that post-published data may be only taken into consideration when considering inventive step if it does not serve as the sole basis to establish whether the application solves the problem it purports to solve. There must be a plausible disclosure of (for example) relevant biological activity in the application as filed. In two key cases[17] involving therapeutic products, a the board of appeal revoked the relevant patent for lack of inventive step, noting that the specification as filed did not contain a "plausible" disclosure of the relevant biological activity. The boards in these cases thus rejected as inadmissible post-published data evidencing the efficacy of the claimed products.

These cases to do not however make it wholly clear whether the requirement for a plausible disclosure requires at least some technical information (such as experimental results) which supports an assertion of biological activity, or whether all that is required is a mere assertion of biological activity which is prima facie credible. Further, there are other cases[18] which suggest that a mere assertion of the relevant biological activity should suffice, if there is no substantiated doubt about the theoretical case made for the efficacy of the invention.

In July 2021, the board in case T116/18[19] therefore indicated at an oral hearing that it intended to refer questions to the EBA on these issues. At the time of writing, the board still needs to write up its decision so the formal referral has not yet taken place but the questions proposed by the board at the oral hearing were as follows (emphasis added):

> *If for acknowledgment of inventive step the patent proprietor relies on a technical effect and has submitted data or other evidence to proof [sic] such effect, such data or other evidence having been generated only after the priority or filing date of the patent (post-published data):*
>
> 1. *Should an exception to the principle of free evaluation of evidence (see e.g. G1/12 reasons 31) be accepted in that the post-published data must be disregarded on the ground that the proof the effect rests exclusively on such post-published data?*

[16] https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5_2.htm, see 5th paragraph
[17] T1329/04 (GDF-9 https://www.epo.org/law-practice/case-law-appeals/recent/t041329eu1.html) and T488/16 (dasatinib https://www.epo.org/law-practice/case-law-appeals/recent/t160488eu1.html)
[18] See for example T578/06 (Pancreatic cells/IPSEN https://www.epo.org/law-practice/case-law-appeals/recent/t060578eu1.html)
[19] Concerning patent No EP2484209 https://register.epo.org/application?number=EP12002626&lng=en&tab=main

2. *If the answer is yes (post-published data must be disregarded if the proof [sic] of the effect rests exclusively on these data): can post-published data be taken into consideration if based on the information in the patent application the skilled person at the relevant date would have considered the effect plausible (ab initio plausibility)?*

3. *If the answer to the first question is yes (post-published data must be disregarded if the proof of the effect rests exclusively on these data): can post-published data be taken into consideration if based on the information in the patent application the skilled person at the relevant date would have seen no reason to consider the effect implausible (ab initio implausibility)?*

Depending on the answers to these questions, which may not come down for 1-2 years, the value of post-published data in European prosecution could either be diminished or enhanced, which in turn could have implications (see below) for patent filing and drafting strategies.

C. Covid-19

The European patent system has coped reasonably well with the pandemic to date. Early on in the pandemic, the EPO was forced to cancel the 2020 attorney qualifying examination and also implemented a wide-scale suspension of many deadlines to help avoid dropped cases but the EPO's own output of written communications remained impressively consistent even then. Examiners got used to working from home more and in general written correspondence, even by then often carried out online, continued surprisingly normally. Unlike the USPTO, the EPO has not introduced specific acceleration/fee reduction measures for Covid-related applications but this is in part because it already has more accessible[20,21] acceleration mechanisms applicable to any application, and meantime it has made available an online tool[22] intended to help researches understand the patent landscape surrounding coronavirus.

But, consistent with trends in working practices elsewhere, the biggest change has been a massively increased use of online communication. As mentioned above, even pre-pandemic much routine correspondence was already exchanged electronically, and of course usage of these platforms has now increased, but almost all "oral proceedings" (OPs), i.e. formal hearings on request if an application is to be refused, or to conclude opposition or appeal procedures, were held in person at the EPO. Videoconferenced ("ViCo" to the EPO) OPs were possible only in pre-grant examination rather than

[20] Notably the so-called PACE programme, by which any application can be accelerated at no extra cost
https://www.epo.org/law-practice/legal-texts/official-journal/2015/11/a93.html
https://www.epo.org/law-practice/legal-texts/html/guidelines/e/e_viii_4_2.htm
https://jakemp.com/en/knowledge-centre/briefings/epo-accelerated-prosecution-procedure
[21] And also patent prosecution highway (PPH) agreements with various other Offices
https://www.epo.org/law-practice/legal-texts/html/guidelines/e/e_viii_4_3.htm
https://jakemp.com/en/knowledge-centre/briefings/requesting-patent-prosecution-highway-pph-in-the-epo-or-uk-ipo
[22] https://www.epo.org/news-events/in-focus/fighting-coronavirus.html

opposition or appeal and relatively little used even there. This aspect of the EPO's work did therefore slow down considerably during 2020 as travel and other restrictions made attendance difficult or impossible.

However, the EPO made a series of very determined efforts to increase the use of ViCo, which first became the norm in pre-grant examination and then in opposition; appeal OPs are subject to slightly different considerations but are in practice also now frequently by ViCo. It was also possible to hold the 2021 qualifying examination online. All of this is nominally subject to later review of one sort or another, and has been controversial enough to provoke a fast-tracked and only partially decisive referral[23] to the EBA, but realistically it is expected that most OPs will be by ViCo even when the pandemic is brought under control. This has taken some getting used to but ViCo OPs do work, in that they now run on widely available internet-based platforms and relatively little is lost in terms of communication with the tribunal. Even the very large, multi-party cases that are more common in life sciences than other areas now take place this way. ViCo also has some advantages, notably reduced travel and hence cost and environmental footprint. For US users of the system in particular, it is now much more practical to attend an OP with one's European attorney than it was before[24]. So this is a cultural shift that may take a few years to become fully embedded to a state where it is clear which OPs should be held in which way but overall it is generally considered a positive change.

D. Brexit

Of course there is no US analogue to this topic but it is worth mentioning as questions are often asked as to what has been its effect on patenting practice and options. In short, the UK's departure from the EU actually makes almost no difference because the EPO is not an EU institution, rather a creation of a separate treaty (the EPC) directly between its member states. There have always been non-EU EPC states, notably Switzerland and Turkey, and a "European" patent granted by the EPO is of course in fact equivalent to a bundle of national patents that all happen to have exactly the same text, which have to be individually brought into effect ("validated") in the member states and litigated/transferred as individual IP rights once the EPO has granted the application. So the EPO continues to grant patents that are effective in the UK in the same way as it did when the UK was an EU member, EPO oppositions continue

[23] https://jakemp.com/en/news/eba-rules-videoconference-oral-proceedings-appropriate-in-an-emergency

[24] Albeit generally starting in the small hours of the morning, though sometimes it is possible for shorter cases to start in the European afternoon or to be delayed until 10/11 AM. It is also important to set up an effective private channel of communication for discussion during the OP, for example a conference call line or parallel videoconference on another platform, and likely also an instant messaging system of some sort. This is admittedly not quite as effective as all being in the same room but again it does work and saves a lot of travel/expense for a big international team and makes it easier to expand the team with, e.g., technical experts whose travel might not be justifiable in all cases.

to apply to those rights as well as the other members of the "bundle" and litigation proceeds nationally as before too. Supplementary Protection Certificates (SPCs), the PTE-like right by which patent term for pharmaceutical and agrochemical products[25] can sometimes be extended on receipt of a marketing authorisation, have also always been granted by the national authorities in another "bundle" so these too are largely (see below) unaffected. This is different than the situation for Community Trade Marks, Registered Designs and Plant Variety Rights because those are so-called "unitary" EU rights, so existing and pending ones had to be partitioned into EU and UK elements and separate applications have to be filed in the EU and UK going forward. The national patent laws of the UK and other EPC member states are also substantively harmonised with the EPC so any divergences in patentability standards that develop should be fairly minor.

One minor point is however that, to facilitate movement of goods on the island of Ireland, Northern Ireland, which is part of the territory of the UK, remains subject to EU regulatory law. This creates a few complexities for SPCs[26] because they sit at the interface between regulatory law patent law, but these are reasonably well mapped out and should not lead to any loss of protection opportunities as long as the rules are correctly followed. Potentially more significant is that, if/when the proposed unitary patent system comes into being, it will not be possible for the new unitary patents (see above regarding other Community IP rights) to cover the UK (or Switzerland or the other non-EU UK member states) but even then the EPO will continue to grant patents effective in the UK so all that will be required will be a separate, cheap validation in the UK and to pay renewal fees to the UKIPO as well as for the EU. The centralised litigation system that will come into being will also not be able to include UK members of "bundle" patents so separate litigation in UK will be required, though equally UK rights will not be at risk of revocation along with the EU ones.

II. Effective claim drafting strategies to avoid pitfalls

A. General points

Patent laws worldwide have a lot in common. Terminology varies but an invention is patentable if it is novel, non-obvious and possible for the skilled person to put into practice. The devil lies in the levels of detail below this.

This inevitably means that, if one builds a patenting strategy, or drafts a patent application, entirely based on US patent law considerations, some issues may arise in

[25] But, in contrast to the USA, not medical devices.
[26] https://jakemp.com/en/knowledge-centre/briefings/supplementary-protection-certificates-for-medicinal-products

the EPO or elsewhere in the world. Near-universal usage of the PCT has huge benefits in terms of costs at the one-year stage and deferral of expensive foreign filing decisions but also means there will be no routine review of the specification at that point by foreign attorneys. Many of the issues that creep in this way are nonetheless remediable during examination, and in some fields of technology relatively few arise anyway. In life sciences, this can be different for a variety of reasons including a different patent-eligibility matrix, an increased tendency to file applications based on proof of concept (or less) and hence potential deficits in written description/enablement and a greater need to make more complex amendments to capture new directions in the research, and in general because life science filings tend to be fewer in number but more complex and valuable per application than in some other fields.

But these differences do not have to be allowed to become pitfalls *per se*. Relatively little detailed familiarity with quirks of EPO practice is required to head off most problems that cannot be addressed during examination. However, a selection of the key US/European differences are below, along with suggestions for avoiding or mitigating the issues they can cause.

B. Specific issues

1. Patent-eligibility

As discussed in section I above, patent-eligibility concepts in Europe differ from those in the USA and, while there may be no outstanding existential questions right now, there are many points on which standards and appropriate claim types differ, and some inventions that are patent-eligible in one jurisdiction but not the other. It is therefore always worth looking at the EPC's list of exclusions and considering whether to contact a European attorney for some informal help at the drafting stage. The value of this of course varies from case to case and depending on how much familiarity the US attorney has with the field but there are some areas (e.g. plant breeding, methods of diagnosis/surgery) where this sort of advice really pays off as it is hard to recast the claims into eligible forms if they do not have something like the "right" structure to begin with.

2. Novelty and obviousness – standards

Fundamental standards do not differ so much but, as noted in section I above, the EPO may be stricter on obviousness than the USPTO, plus there is of course case-to-case variation that can mean that one case goes more easily in the US and another in the EPO. There is not much that can be done about this before examination

begins as inventive step always has a subjective dimension and, in contrast to patent-eligibility issues, it is unlikely to be possible to get definitive local advice ahead of filing. However, it is still worth knowing that a more searching examination of obviousness may be coming and beginning to build a case for that in the introduction of the specification – not only what is the invention but what is the most relevant art and how is the invention advantageous over it? These statements are powerful because they are the first thing the examiner reads and can help to establish the invention in a positive light from the outset, whereas if the specification does not really explain what the invention is and why it is an improvement, the same information may be met with scepticism later on.

3. Novelty and obviousness – inventor disclosures

It is well known that the EPC allows no grace period for inventor disclosures but this still has the potential to cause problems. In cases where the invention has been fully disclosed ahead of filing, the answer may be simple, i.e. do not file in Europe, but there are also situations where one can proceed by recognising that some claims may be available but these will be narrower and will have to be novel and non-obvious over a partial disclosure. There is no obligation to provide the disclosure to the EPO in an IDS-type format but it is beneficial to have fall-back positions, usually dependent claims, that are intended to be promoted to independence in EPO examination.

Also important is that the EPC does not give any special status at all to inventor-originating prior art. So not only does a disclosure before the US provisional is filed count against the application in Europe in the end, also a disclosure in the priority year counts against any information that is added by the one-year stage. This combines with the EPO's stricter position on priority entitlement to favour more complete drafting of provisional applications than is sometimes necessary for purely US purposes (see below regarding priority for more detail).

4. Written description and enablement-type issues

With reference to section I above, standards on these issues are also not radically different. However, the USPTO may be stricter overall but more receptive to post-published data. This can create tensions as to when to file and how much data to include. Regarding when to file, many US applicants tend to file early to beat the potential competition even if they do not have a lot of experimental data, whereas a later and more supported filing may have a better chance in Europe. There is no simple answer to this but it is worth recognising the trade-off and (a) avoiding

inventor disclosures in the priority year if possible (see above), (b) adding in data during the priority year if possible, (c) considering what is best overall and in the short and long terms – the most established life science players conversely tend to file quite late and with a lot of data, but not everyone can afford that luxury; and in any case (d) including as much of the rationale as possible as to how and why the invention is expected to work as this (see Section I above) is the springboard to being permitted to rely on post-published data later.

Sometimes, however, there is data in hand but a reluctance to include it all as it will of course be publicly accessible when the application publishes 18 months later. In Europe, there has never been a best mode requirement and there is no duty-of-candour obligation to file everything one has either. However, it is generally better to bite the bullet and include more rather than less. Trying to "anonymise" data[27] also tend to backfire as examiners and opponents attack the anonymised data as inadequate even if it is only really supposed to be providing proof of principle.

5. New matter and basis for amendment

This is probably the single biggest problem encountered by US applicants in the EPO. The EPO is extremely strict on amendments in a formal sense. Added subject matter under the EPC[28] is in principle similar to the new matter concept in US practice but this is like saying that a tiger is in principle similar to a house cat. Case law under the EPC does not strictly compel literal support for all amendments, as what is implicit can be made explicit and one is not supposed to have to use exactly the same words, but examiners often behave as if it does, as the standard is that the subject matter of an amended specification has to be "clearly and unambiguously derivable" from the application as filed.

In practice the best amendments are those that arise from simple claim combinations and/or or the addition of a single, clearly generally applicable feature from the description to a claim. Amendments that represent "intermediate generalisations" or require "selection from lists" of possibilities are problematic as the EPO (and more so, an opponent after grant) tends to argue that they represent new combinations of subject matter that were not specifically itemised in the original disclosure.

[27] For example by presenting results of immunisation with "Antigen A" or obtained with "Compounds 1-20" rather than giving names or structures.
[28] Article 123(2) EPC: The European patent application or European patent may not be amended in such a way that it contains subject-matter which extends beyond the content of the application as filed.

These issues can be very problematic as, if a desired amendment cannot be made to address an art or enablement objection, either a weaker broader claim has to be defended instead or potentially the application has to be abandoned. As new matter is a formal issue rather than a substantive one, it also usually does not help to argue that the invention contained in an amended claim is patentable or that the examples back it up: what one is looking for is the right words.

The only way to avoid these issues is to plan ahead by building in to the specification extensive fall-back positions that can reliably be converted into claims if the broader claims fail. A well thought-through cascade of dependent claims, especially multiply dependent ones, can help a lot, as can calling out preferred combinations of features in the claims or description, and listing out final fall-backs in terms of, for example, single disease states or compounds. It is impossible to overstate the potential value of this level of thoroughness in drafting.

6. Priority entitlement – textual and substantive issues

The EPO is also much stricter on priority entitlement than the USPTO, effectively working to the same near-literal standards as for new matter (see above). Therefore, if a bare-bones provisional filing is made for the sake of speed and cost, there is a good chance that later edits to upgrade it do not have priority. This is not a reason not to make such edits anyway, in case nothing turns on priority entitlement, but it does speak in favour of making sure that at least the key independent and dependent claims are fully thought through at the provisional stage, as then at least those have priority. Without that exercise, it is almost impossible to write a broad (or nuanced) priority-entitled claim later, because the basic scientific concepts may be in the provisional but the right language will usually not be.

By the same token, if (see above) there is an inventor disclosure in the priority year, this will count as prior art against the later edits or added material. The combination of a “coversheet” provisional without claims (or similar statements of invention) and an inventor disclosure soon afterwards is therefore usually disastrous for European protection. In situations where a disclosure is in prospect, if solid European protection is desired, there is no alternative but to write a full specification from day one regardless of time or cost pressure.

Also worth keeping in mind is that, for priority to be valid, the priority document has to be enabling. For this reasons, the same written description/enablement considerations apply at the provisional filing stage as at the full application stage.

7. Priority entitlement – formal and assignment issues[29]

There is also an increasing trend in EPO oppositions towards impugning priority entitlement based on allegations that the inventors did not properly transmit their rights to the applicant (assignee) before the PCT or one-year European application was filed. Where that is actually correct, it is very serious because the EPO firmly requires effective transmission of the right to claim priority from the application before the PCT or one-year European application is made so this cannot be corrected later (potentially bringing in intervening disclosures if priority is lost).

US applicants are at particular risk in this regard because the pre-AIA US practice of filing provisional applications in the names of inventors has not been entirely superseded by assignee filing as might have been expected. This can therefore lead to situations where the inventors are the only applicants on the provisional and the assignee is the only applicant on a PCT application (as US law no longer requires the inventors to be named as PCT applicants too). There is however no problem with this if the inventors have correctly transmitted their rights.

Some rules to follow on this are therefore: (a) make the provisional an assignee filing if at all possible, and then file the PCT/European application in the same name – in which case no priority question can arise; (b) if for some reason the inventors have to be the provisional applicants, always get assignments promptly after filing, including of both the application as filed and the right to claim priority from it; (c) if for some reason that has not happened by the time of the one-year filing, get local European advice on how best to proceed, possibly including filing the PCT/European application in the name of the inventors (or jointly between them and the assignee) and transferring it (or their share in it) after filing instead – as the right to grant as opposed to that to claim priority can be perfected any time before grant; and (e) if such an issue comes to light too late for any of (a-d), consider whether the inventors' rights can be said to have transferred automatically by virtue of some contract, usually of employment, with the assignee – this often works as a last resort but only if the language of the contract makes it clear that the rights in inventions are transferred[30] to the employer rather than that they will be transferred separately as they arise.

[29] https://jakemp.com/en/knowledge-centre/briefings/priority-entitlement-in-europe-current-best-practice-following-board-of-appeal-decision-t84418
[30] For example, by *"does hereby assign"* language.

A further complication can arise where there are is more than one applicant (including more than one inventor-applicant). This is the issue that caused the well-known loss of the Broad Institute's CRISPR patent in the EPO in 2020[31]. The key point in these situations is that the EPO regards the applicants on the priority application as a "legal unity" that holds the priority right. All of the applicants who comprise that legal unity have either to be applicants on the PCT/European application or to have transferred their rights to an applicant who is. Never simply drop an applicant, even if the PCT/European application does not contain their contribution to the provisional invention, always deal with these situations by agreement between the applicants[32]. By contrast, adding an applicant at the one-year stage is not an issue, as the original applicants are still included and still have their right to priority.

8. Unity of invention and related points

All US practitioners in the life sciences will be familiar with the way the USPTO fragments cases via restriction requirements. The EPO can be similarly brutal but usually along slightly different lines. In the EPO, there will seldom if ever be a restriction by claim category (e.g. DNA vs protein) but "bundle" inventions where the applicant claims many different antibodies, genes, markers etc. will typically attract a usually insurmountable non-unity objection. Coupled with the fact that European divisional applications can be filed in similar ways to those in the US[33] but at greater cost because renewal fees due pre-grant have to be bac-paid based on the parent filing date, this means that it is often prohibitive to file enough divisionals to capture all the subject matter originally claimed.

This may not be as big an issue as it seems, as frequently the purpose of the "bundle" applications is to allow one or a few candidates to be chosen later and the others discarded, and also there may be nothing that can be done to unify the various inventions anyway. However, there are some situations where there is, for example where some of the genes have related sequences or are homologues from different species in the case of "families" of engineered/humanised antibodies that are derived from an original "parent". In these cases, it pays not simply to hold out each item as an entirely separate entity but rather to try to present them in terms of the way in which they are related. This might be done via a general formula or consensus sequence in some cases, failing which by including an explanation of the relationship and/or a sequence alignment highlighting the similarities. This can

[31] See footnote to header of this section
[32] Which may, for example, lead to a pattern of assignments and separate or divisional filings; obviously more complex but will not compromise priority entitlement.
[33] At any time pre-issue, with multiple generations of division also possible.

save a lot of money in the right cases, as it is hard to get the examiner to go back on a unity objection once it has been raised so trying to head one off at the drafting stage is the best hope of keeping more subject matter in one application.

9. Claim numbers and structures

As well as renewal fees, EPO claims fees can also get very expensive. The cost of each claim (independent or dependent, including multiply dependent) over the 15th is in principle approximately USD 300 and claims over the 50th are over USD 600. In fact, few of these fees are paid because European attorneys edit claim sets down on or shortly after filing to avoid or minimise these costs. In life sciences, where claim numbers tend to be high and there may be many claim categories and different independent claims, this can however lead to very complex and unwieldy claim sets that attract issues during examination so it is worth planning ahead to the extent possible.

This could for example take the form of being ready to focus on some subject matter by around six months from European regional phase entry[34] of a PCT application and to excise the rest or reserve it for divisionals. Or, if a parallel US application is being filed at the 12-month point and the PCT will not be brought into the US national phase, some applicants tailor their PCT claims more to EPO requirements rather than simply copying the US national specification entirely. The US claims can then be retained as a list of non-claim embodiments in the description if desired. This may not be an approach that works for every case but it can streamline matters in the right ones. It also offers the opportunity to include multiple dependencies that cause issues in the EPO but are routinely permitted in Europe and most other jurisdictions worldwide. Conversely, if US-style claims are used in the PCT application, it is possible to include a set of more European-style ones as embodiments.

A related issue is that the EPC[35] in general only permits one independent claim per claim category (e.g. one claim to DNA, one to protein, one to an antibody, one to a treatment and so on). This is a significant difference from US practice where multiple, overlapping independent claims are common and there is often a desire to have a narrow but independent "picture" claim for litigation purposes. This is an issue that can in general be addressed by amendment in European examination but

[34] Which is when the amendments need to be entered under Rules 161/2 EPC
[35] Rule 43(2) EPC: … a European patent application may contain more than one independent claim in the same category (product, process, apparatus or use) only if the subject-matter of the application involves one of the following: (a) a plurality of interrelated products, (b) different uses of a product or apparatus, (c) alternative solutions to a particular problem, where it is inappropriate to cover these alternatives by a single claim.

again one that is worth foreseeing. The reason for this is that, if the various independent claims overlap rather than "nesting" one inside another, it is not possible simply to make one dependent on another and some scope may be lost when one has to be chosen over another. Therefore, even if there are also others, it pays to make sure there is a "master" independent claim in each category, with dependent claims to the major fall-back positions coming off it. Then the others can more easily be simply struck out this becomes an issue.

10. Biological deposits[36]

    Biological deposits also tend to cause issues for US applicants at the EPO. The fundamentals are familiar in that both the USPTO and the EPO work to the Budapest Treaty so both accept reliance on deposits for enablement but there are some differences in that:-

    - The always EPO requires the deposit to have been made before the filing date (or the priority date if priority is to be valid) and hence does not recognise deposits made during examination.

    - If the deposit is made before filing but the deposit number is allocated too late to be included in the specification, it can be provided later but this has to be done by 16 months from the priority date – not so bad in the case of a direct European filing where 16 months is four months after filing at the EPO but can be problematic in PCT-based cases as then the number has to be submitted to the International Bureau during the PCT international phase, which is easy to forget and not correctable after European regional phase entry.

    - Unless an authorisation from depositor to applicant is filed in the same way as above before 16 months from priority, the EPO insists that the depositor and the applicant are the same entity, and this applies even where the two are members of the same overall group of companies – which can be very difficult or impossible to address later, so it is always worth making clear that the deposit must be made in the same name that will be used for the patent application, or contacting local European counsel for advice on an authorisation if that is no possible.

11. Co-applicants and licensing/assignment

[36] https://jakemp.com/briefings/introduction-to-biological-deposits-at-the-european-patent-office-and-under-the-budapest-treaty/379 and https://jakemp.com/briefings/biological-deposits-strategic-considerations/379

In the USA, it is permitted and normal for co-applicants to license and assign their rights individually but this is unusual globally and most European countries do not permit it. In the UK, for example, independent licensing/assignment is only possible by agreement between the co-applicants to that effect. This is a potential pitfall when collaboration agreements are either lacking or drafted with global effect but based on US legal thinking. For these reasons, it is where possible good to avoid having co-applicants in the first place[37] but, if there have to be co-applicants, making an agreement that separate assignment/licensing is possible if that is what is desired.

III. Conclusions

In different ways, both the foregoing sections of this paper highlight similarities and differences between US and European patent practice. Section I contains what is hopefully some welcome confirmation that, even though the parallel European landscape has its own complexities, the same specific patent-eligibility issues that have plagued the US system recently are generally not also issues in Europe, and are also unlikely to become issues. On patent-eligibility in life science, we mostly know the rules at the moment. Written description and enablement-type issues are significant but not more so than in the USA and the upcoming EBA referral on "plausibility" should help to clarify the parameters for reliance on post-published data. Regarding section II, differing traditions and mind-sets around drafting and filing patent applications mean that Europe can be a minefield for US applicants and practitioners (and vice versa!) - but it does not have to be one if points such as the above are taken into account.

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30 August 2021

[37] For example by having one assign to the other and agreeing that the assignee will take the commercial lead in return for remuneration and/or a license to practice the invention