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Medical treatment methods, medical indication claims and patentability: a quest into the rationale of the exclusion and patentability in the context of the future of personalised medicine

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***203** Abstract

This contribution discusses the thorny issue of the rationale of the exclusion from patentability of medical treatment methods and the patentability of medical indications. This quest is the consequence of our earlier findings that medical indication patents present a real life risk for many players in the medical chain, i.e. the generic manufacturer, the clinician and the pharmacist of patent infringement (see to that effect our contribution at [2016] I.P.Q., 151). We come to the conclusion that the rationale for the exclusion from patentability of medical treatment methods is not very clear and can be interpreted very broadly. It has changed over time but seems now to be based on a rather wide socio-ethical rationale, aiming at protecting healthcare, which, even if justified, seems to be so broad that not only medical treatment methods but also the very patentability of pharmaceutical products can be subsumed under it. We also conclude that the rationale for allowing medical indication patents is equally not very clear, and their allowability was most definitely not a "love at first sight" affair with the legislature. It is submitted that certain medical indication patents sit very close to the activities of clinicians, which makes the argument that medical indication patents do not directly touch the physician not always correct. It is argued that, looking at the historical rationale of both the exclusion from patent protection of medical treatment methods and the patentability of medical indication inventions, there is some force in arguing that medical indication patents are not desirable. We formulate a number of possible solutions. It is argued that abolishing the exclusion from patentability of medical treatment methods, even though feasible if accompanied by the introduction of a therapeutic freedom exemption, is in view of the historical rationale of the exclusion, at least in EPC territories, not very likely to find support. It is further also argued that abolishing medical indication patents could be such a drastic action that it might come at the detriment of at least some genuine innovation in medicinal research, and would require further reflection.

Introduction

In an earlier contribution in this Journal,¹ we provided a very detailed analysis of the legal technical mechanics of second medical indication claims, of how they can be protected and are being enforced, and of the problems which such enforcement may present to the affordability of healthcare, and we presented a number of solution to mitigate the (potential) risks which such enforcement may present for all players *204 in the healthcare system, i.e. the physician, the pharmacist, the generic drug manufacturer and, where applicable, also the generic drug distributor or wholesaler.

Indeed, we established that the legal system of medical indication claims can lead to results which are not necessarily in the best interests of society. In particular, we established that in the case of off-label use, all players in the healthcare system run a credible risk of infringing medical indication patents. For the generic manufacturer, this could even be

the case despite a carved-out market authorisation according to which the generic drug so authorised is not put on the market for a patented medical indication. The case law seems to suggest that as long as such a generic manufacturer knows that the drugs he supplies will be used in the treatment of a patented medical indication, infringement seems to have been established. As any generic drug manufacturer knows that there is always off-label use by physicians and/or pharmacists, such seems sufficient to trigger a liability claim. The physician prescribing a generic drug off-label, i.e. for a patented medical indication for which the generic drug has not been authorised, equally runs the risk of infringement liability, as is also the pharmacist dispensing generic drugs for patented medical indications. I refer to my contribution in issue 2 for a detailed analysis.

We have on that occasion also provided a number of possible solutions. Some of those suggested the abolition of second medical indication claims and/or the abolition of the exclusion of medical treatment methods from patentability. I again refer to the previous issue of this Journal for more details.

And this brings us then to another thorny issue in patent law. Indeed, under art.53(c) EPC 2000, "methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body" are excluded from patentability. The rationale for this exclusion was that it was deemed unethical to see physicians limited in their daily practice by patents. As has been demonstrated in my contribution in the previous issue of this Journal, and as I will establish also in the present contribution, certain medical indication patents can sit very close to medical treatment methods. This is in particular the case for dosage regimes.

The aim of the present contribution is then also to evaluate what historically the rationale has been for excluding medical treatment methods, what has been the rationale for allowing medical indication patents, how the two coexist, whether there are reasons to assume that certain medical indication patents are in fact nothing more than a legal "trick" to avoid falling under the exclusion of medical treatment methods, and, if the answer to the latter question is positive, whether that requires reform, also in view of the genuine infringement risks for all players in the medical chain relating to medical indication patents.

It will be demonstrated that the historical rationale for excluding medical treatment methods from patentability is not very clear and has changed over time. A rather wide socio-ethical rationale, aiming at protecting healthcare, even if justified, seems to be so broad that not only medical treatment methods but also the very patentability of pharmaceutical products can be subsumed under it. The rationale for allowing medical indication patents is equally not very clear, which is not surprising, as the legislature was also in this respect very concerned about the clinician's freedom of activity, and at least to some it seemed that medical indication patents could interfere with that. However, a successful campaign by the pharmaceutical industry convinced the legislature that incentivising innovation in already existing molecules deserved patent protection.

It is submitted that certain medical indication patents sit very close to the activities of clinicians, which indicates that the argument that medical indication patents do not directly touch the physician is not always correct. It will be argued that, looking at the historical rationale of both the exclusion from patent protection of medical treatment methods and the patentability of medical indication inventions, there is some force in arguing that medical indication patents are not desirable. However, it is also argued that such a drastic action might come at the detriment of at least some genuine innovation in medicinal research, and would require further reflection. It is finally argued that abolishing the exclusion from patentability of medical treatment methods, even though feasible if accompanied by the introduction of a therapeutic freedom ***205** exemption, is in view of the historical rationale of the exclusion at least in EPC territories not very likely to find support.

Exclusion of medical treatment methods from patentability

Historical evolution

Medical treatment methods have been excluded from patentability for quite a while, at least in Europe.² This section will analyse more in depth the historical background and rationale of that exclusion. The rationale for the non-patentability of medical treatment methods has seen a rather confusing history, and over the years, legislatures have grappled with defining the exact reason why such methods should not be patentable. That alone gives some reason for concern, as a changing rationale for having such exclusion could be evidence that there is in fact not a good reason to exclude such methods at all. This somewhat confusing history has been demonstrated not only at the level of the EPC, but also at the national level, where similar changing reasons for excluding those methods have been advocated over the years.

It could be said that the goal has always been to guarantee the therapeutic freedom of the physician. There was a desire to guarantee access to medical procedures and therapies for the physician.³ However, the route towards this goal has been quite a bumpy one. The present rationale of the exclusion seems to be inspired by socio-ethical and public health policy considerations.

It is seen as ethically responsible and in the interest of public health to have no patent protection for such methods.⁴ Or, as the Australian Federal Court said in the *Bristol Myers Squibb Co v F H Faulding* case,

"the opponents to the grant of a monopoly in respect of medical and surgical processes raise objections that can be put into two broad groups: (i) the adverse effects on the provision of medical care; and (ii) the adverse effects on medical progress and education. In addition there is the related 'ethical' question whether a medical practitioner (medical and surgical processes are usually invented by a medical practitioner) should be entitled to patent her invention consistent with her obligation to provide medical services to humanity. Perhaps the most powerful argument against patenting is the idea that a patient may be denied medical treatment that she needs. It is certainly the most emotive of the arguments. It presumes that a medical practitioner may be unable to obtain the right to use a particular process, or may not be able to do so within due time, and therefore will be unwilling to undertake the process on her patients for fear of legal action. It is also said that the traditional commitment of medical practitioners to develop, share and disseminate new knowledge will be repressed. That is to say, the medical practitioner who is seeking to discover a new medical or surgical process will deliberately withhold new medical knowledge from her colleagues so as to protect her discovery and enhance her ability to obtain patent protection for financial reward. Another aspect of this argument is the potential conflict of interest which could arise when a medical practitioner has an economic interest in a patent: a conflict that might result in the practitioner not acting in the best *206 interests of her patient. A further aspect of this argument is the suggestion that the existence of a patent is a disincentive to further invention."⁵

The *travaux préparatoires* of the EPC 2000 provide a more explicit socio-ethical rationale for the present-day exclusion. The exclusion was moved to art.53 EPC, which deals with exclusions from patentability, whereas it was under the EPC 1973 to be found in art.52(4), with a rationale that such inventions lacked industrial applicability:

"The exclusion of methods of treatment and diagnostic methods currently referred to in Article 52(4) EPC has been added to the two exceptions to patentability which appear at present in Article 53(a) and (b) EPC. While these surgical or therapeutic methods constitute inventions, they have been excluded from patentability by the fiction of their lack of industrial applicability. It is undesirable to uphold this fiction since methods of treatment and diagnostic methods are excluded from patentability in the interests of public health. It is therefore preferable to include these inventions in the exceptions to patentability in order to group the three categories of exceptions to patentability together in art.53(a), (b) and (c) EPC."⁶

Historically, however, the reason for excluding medical treatment methods from patentability was not inspired by ethical or societal reasons, but by more technical legal arguments. The *travaux préparatoires* of the EPC 1973 say expressly that there was some trepidation in changing existing practices in Member States, where, at least in some, medical treatment methods were already excluded from patentability.⁷ For quite a few years, the exclusion from patentability of medical treatment methods was in draft texts to be found in the general provision of what is now art.52 (then art.9) dealing with subject-matter which does not constitute patentable subject-matter.⁸ In 1973, and without much if any clarification, the addition was made in the draft text that such medical treatment methods were deemed not industrially applicable, thus laying down a rationale that such inventions are in principle patentable subject-matter, but are excluded as not being industrially applicable, probably influenced by practices in some of the Member States, about which more further. In conclusion, the *travaux préparatoires* of the EPC 1973 do not inform us much as to the rationale of the exclusion of medical treatment methods from patentability, apart from the fact that such exclusion seemed to have been largely inspired by future Member State national practice from which the drafters of the EPC did not want to deviate much.

That brings us then to look for the rationale in national practice. In Germany, the legislature cast the exclusion into the Patent Act only in 1976. The first decision dealing with the issue can be found in the so-called Badewasser decision of the Appeal Division of the German Imperial Patent Office in 1904.⁹ The reasoning behind the refusal to grant the patent was that it was not industrially applicable. This rationale was used for quite some time in the subsequent case law. In the post-war case law, socio-ethical arguments started to gain influence, in both the case law¹⁰ and the literature.¹¹ In the seminal Glatzenoperation case of 1967,¹² the German Federal Supreme Court set the standard. In a case relating to a medical treatment for baldness, the court held that the industrial application requirement was not fulfilled, as the medical *207 profession was not a trade. There are socio-ethical reasons why the medical profession is not considered to be a trade, as a physician should not be influenced by business considerations in treating patients. Public health together with the objective of the medical profession to treat patients constitute the socio-ethical ground for considering medical treatments to lack industrial application.¹³ That decision did not

"stand in the way of allowing a use claim for a substance which serves to treat a disease. The use of a substance for the treatment of a disease, utilizing the healing effect of the substance, ensues not exclusively through the application or prescription of the drug by a physician. It ordinarily also encompasses a number of transactions which do not, like the medical activity, lie outside the scope of commercial use, such as the formulation and preparation of drugs, their dosage and their end-use packaging. All these transactions which precede medical application are encompassed in the use claim applied for".¹⁴

In the UK, prior to the [UK Patents Act 1977](#), there was no statutory provision excluding medical treatments.¹⁵ Case law invoked [s.6 of the Statute of Monopolies](#)¹⁶ to conclude that medical treatment methods are no "manner of new manufacture" and can hence not be patentable. In the seminal [In the Matter of C and W's Application](#) case, it was held in this connection that

"what is meant by 'new manufactures' is something associated with the manufacture or sale of commercial products as I think is made clear by the latter words of [Section 6](#), which say, 'so' as also they be not contrary to the law nor mischievous to the State, by raising 'prices of commodities at home' or hurt of trade, or generally inconvenient'. I think, therefore, we must start with the assumption that an invention within the meaning of the [Patents Act 1907](#), is an invention for a manner of new manufacture that is in some way associated with commerce and trade. It is quite plain that that does not merely mean that it must be a product. A manner of new manufacture may be a thing newly made, or a substance which, if made before, is improved in its manufacture; or, quite apart from that, it may be a machine or a process that can be used in making something that is, or may be, of commercial value. If I am right in that view, the question which I have to consider is whether the process described in the present Specification is something to be used in the making of an object that is or may be of commercial value or is a process adapted to that end. I find it difficult to see that it is. It

is in fact a process by which certain well-known electrical apparatus is to be applied for the purpose of extracting lead from living objects. Further, I think, on a true reading of the Specification, those living objects are meant to be human beings. So far as human beings are concerned, it cannot be suggested that the extraction of lead from their bodies is a process employed in any form of manufacture or of trade, though the human being may be a better working organism when the lead is extracted".¹⁷

This basis for excluding medical treatment methods was over time put in doubt. *208¹⁸

In [Schering AG's Application](#), the court held that:

"It is no doubt sensible that a person who is able to produce a substance which, for example, would cure or prevent cancer should, subject to safeguards, be offered a limited monopoly as a reward, and the possibility of such monopoly protection has undoubtedly resulted in an enormous investment in research in the medical field. If this position is accepted, it is a little difficult to see why someone who by research effort devises a new method of using a known substance to achieve equally beneficial results should be denied patent protection."¹⁹

This seems to suggest clearly that Whitford J was not a proponent of the exclusion of medical treatment methods from patentability, and felt that it was somewhat illogical to conclude such an exclusion, which he also explicitly said:

"Although it is difficult to see any logical justification for the practice in relation to processes for medical treatment, if the object of the system is in truth to give hope of a reward to people whose research and industry results in valuable products or processes, it does appear that in 1919 and again in 1949 Parliament must have proceeded upon the assumption that patents for processes of medical treatment as such were not within the contemplation of the statute."²⁰

However, he confirmed the practice established since the [C. & W.'s Application](#) decision, but added that

"in the circumstances of today, when it must be recognised that research on an ever-increasing scale at great cost may be, and often is, necessary if certain problems in the field of medical treatment are to be overcome, it may well be desirable that the legislature should review the question as to whether applications for patents for medical treatment generally or to some less, and, if so, to what, extent should be permitted. An opportunity to do this will arise in the near future if and when the Banks Committee report is implemented. On a consideration of the terms of the statute as it now stands, it does, however, seem that claims to processes for medical treatment must be considered as being excluded from the scope of the Act and the practice of the office. Whatever, therefore, the origin of the exclusion may be, in so far it relates to processes for the medical treatment of human beings to cure or prevent disease, it must be considered sound".²¹

Whitford J further also referred to the Australian NRDC case, where the High Court of Australia had held that:

"It is not of course possible to treat such a statement as conclusive of the question. The need for qualification must be confessed, even if only in order to put aside, as they apparently must be put aside, processes for treating diseases of the human body."²²

That gave Whitford J more support that also the High Court of Australia was not sure about the rationale of such exclusion.²³

In [Eli Lilly & Co's Application](#), the Patents Appeal Tribunal held that:

"It has long been established that claims to methods of medical treatment should not be accepted and this appears to have been in the contemplation of Parliament when the 1949 Act was passed (see our judgment in the [Schering](#) case). The reasons for such an exclusion appear to us to be based in ethics *209 rather than logic but if there is to be a change of policy, which would appear to us to be sensible, this ought in our view to be effected by legislation rather than by interpretation." ²⁴

This decision hence constituted yet another indication that an exclusion of medical treatments from patentability is likely to be an illogical measure to take, and that as a consequence intervention by the legislature was required to settle the matter. Interestingly enough, Graham J and Whitford J were also of the belief that the exclusion as it had become common practice should be based on ethical grounds.

The conclusion of the tribunal that medical treatment methods were not patentable was later confirmed by the Court of Appeal in the [Upjohn Co \(Robert's\) Application](#) case. ²⁵ In 1977, the exclusion was finally codified in the [UK Patents Act 1977](#). ²⁶ However, this codification did not take place based on purely ethical grounds, but it was phrased in the same way as the EPC read, i.e. that medical treatment methods lack industrial applicability.

Evaluation

The historical analysis of the medical treatment exclusion leaves the reader somewhat dissatisfied. From not being excluded from patentability at all, medical treatments became over the course of time excluded from patentability based on a variety of policy grounds, which are not all very consistent, if not inconsistent. It is also surprising that the drafters of the EPC 2000 in fact explicitly admitted that previous policy reasons for not granting patents to such methods were ill conceived.

Especially, also looking at UK case law demonstrates that the rationale for excluding medical treatment methods has to a large extent been bedevilled with not only uncertainty as to whether it was a good idea in the first place to exclude such methods from patentability, but also to a large extent with a lack of a clear foundational argument or principle.

The underlying rationale for not patenting such methods is that it would be deemed unethical to interfere with the daily activities of the clinician and the interests of health, a very wide-ranging concept indeed. It was not made clear, however, why that would necessarily be much more the case in medical treatment methods than for products used in such methods, the latter being perfectly patentable. That means that the exclusion from patentability of medical treatment methods does not seem to have very sound foundations, or, in the alternative, has such deep foundations that questions can equally be asked about the patentability of products used in such treatments, as they will also have an impact on health. That will be even more the case if one takes the example of medical indication patents which, as we will see below, have come to sit very close to the activities of the clinician.

Historical development of medical indication claims

Introduction

As we have seen in our contribution in an earlier issue of this Journal, medical indication claims have not been uncontroversial and they do constitute a major deviation from the principle of absolute novelty. That as such is a good enough reason to try to establish how this concept came into existence in European patent law. Medical indication claims are a relatively recent phenomenon. This fact has a number of largely historical rationales. Several EPC Member States did not allow product protection for pharmaceuticals for quite some time. For example, in Germany, product protection

for pharmaceuticals has only been *210 allowed since 1968.²⁷ Absent such product protection, there was not much point in discussing purpose limited further protection for pharmaceuticals.

Secondly, the shadow of the exclusion of medical treatment methods has also been quite long, and in early discussions, as we have seen, the societal and ethical reasons for not allowing patents for medical treatment methods have also influenced the discussion on further medical indication patents. It was thought in some Member States that, by allowing further medical indication patents, the exclusion for medical treatment methods would be hollowed out. Even though the discussions on the exclusion from patentability of medical treatment methods and the patentability of medical indications took place simultaneously, it was much easier to reach a consensus on the non-patentability of medical treatment methods, as they were considered to be undesirable as interfering with the daily work and practices of the medical profession, and for the reasons mentioned earlier. Furthermore, they were already excluded from patentability in several of the later EPC Member States at the time of negotiating the EPC, which created as such sufficient momentum not to touch upon these existing national practices. That meant that once an agreement was reached on the exclusion from patentability of medical treatment methods, the next step was to evaluate whether further medical indications could be patentable subject-matter or not.

Thirdly, there was also the further complication that there were divergent evolutions in Member States. Some did categorically refuse to discuss the issue, while others already had some form of limited further medical use protection in place.²⁸ One has to see the birth of medical indication patents against this background.

A short "aide-memoire" on what medical indication patents are is helpful here.²⁹ A first basic principle of patent law is that one can patent a new chemical entity as such as long as it does not form part of the state of the art. Under the concept of absolute novelty in patent law (for the EPC, see art.54), i.e. anything which forms part of the state of the art can no longer be the subject of a patent, it would normally not be possible to obtain patent protection for a chemical entity or molecule once it forms part of the state of the art. However, after a successful campaign from the pharmaceutical industry that absent protection for further medical uses of an already patented or known substance, innovation into and development of new drugs would be stifled, the legislature inserted a provision to the effect that a first medical use of an existing molecule could still attain patent protection (art.54(5) EPC1973), thus creating an exception to the aforementioned novelty rule. The seminal G5/83 **EISAI** case extended medical use protection also to second and further medical uses of an existing molecule.³⁰ This principle was in the EPC 2000 codified in the sense that it is now also possible to obtain patent protection for a product for the use in the treatment of a certain medical indication (art.54(5) EPC 2000), while the first medical indication would cover the product for the use as a medicament (art.54(4) EPC 2000).

Historical development

The *travaux préparatoires* of the EPC do not reveal too much about the specifics of medical indication patents. Worth mentioning in this connection is also that neither the Strasbourg Convention³¹ nor the PCT,³² the two conventions on which the EPC is based, contained at that time any provision relating to medical indication patents. *211

The issue was for the first time mentioned in the Proceedings of the 12th meeting of the Patents Working Party, where Van Benthem raised the question of whether a therapeutic method should be regarded as an invention. The chairman recorded after a discussion of the question that "therapeutic methods were not patentable under the national laws of the six Member States and no delegation on the Working Party wanted European law to depart from the principle".³³

The issue of the patentability of pharmaceutical products was subsequently discussed more in detail during the meetings of the Working Party from 1 to 12 June 1964.³⁴ It was on that occasion that the issue of first medical indication patents was first discussed. In fact, during the meeting, not only first medical indications but also further medical indications

were discussed. It is interesting to note that in the hypothetical examples given, the first medical indication was a very specific one, and not the very broad and generic one which later made it into the EPC. Fressonnet raised on that occasion the question of what would be the law if someone developed yet another medical application, and pointed out in that connection that such would not be patentable under French law. A number of objections to such a system were also examined. One was that there was a fear that patent protection would lead to insufficient production. Another was the fear that allowing medical indication patents would lead to excessive prices for medicaments in view of the patent protection. A last objection raised was that it was believed at that time that the pharmaceutical industry would, by the introduction of such system, bear the burden of patents protecting the chemical industry, as any medical indication patent is dependent on the chemical molecule patent, necessitating the pharmaceutical industry to pay licence fees to the chemical industry for the use of those chemical molecules.³⁵ In subsequent meetings in October 1964, the issue was again discussed.³⁶ It was concluded that medical treatment methods of the human body would become non-patentable, and that the issue of medical indication patents would have to be deferred.³⁷

When an amended Draft was presented in January 1965, there was a provision added in the then art.9 (which eventually became art.52 EPC 1973) referring to the non-patentability of "methods of therapy, including diagnostic methods".³⁸ No further mention of pharmaceutical patents was made. By the time the text made it to the First Preliminary Draft of a Convention Establishing European System for the Grants of Patents in 1970, the text had been amended into the then art.9(2)(e) which excluded the following from patentability: "therapeutic or surgical methods for treatment of the human body, and diagnostic methods".³⁹ There was still no mention of the products used in such processes or of any other related issues regarding the patentability of pharmaceutical products.

During the discussions of the Working Party in October 1971, the issue of pharmaceutical patents was once again covered. It was reported that interested circles had been pleading for the introduction of patent protection for further applications of drugs, so as to give an incentive to the industry to invest in such innovations. However, it was once again held off with the argument that the reasons for introducing a provision allowing patents to be granted for new therapeutic applications of known substances were not *212 sufficient to justify a deviation from common practice in some of the Member States, where it was not possible to patent such further applications.⁴⁰

During the subsequent discussions, more and more comments were received from interest groups and industry associations asking for the introduction of a provision allowing new therapeutic applications to be patentable. It was argued that in the interest of developing medicaments and public health in general, further applications should be patentable, as absent such incentives, the pharmaceutical industry would concentrate its efforts on developing new products only, which would cost a lot of time and money, and there would be much uncertainty as to the outcome.⁴¹

In its Note of 28 February 1972 (BR/GT I/152/72), the French delegation had drawn a distinction between therapeutic methods and the products, substances or compositions for therapeutic use. It felt that the question whether a new therapeutic application of an active principle known in therapy was patentable should be clarified. The discovery of an application, in no way deriving from the known pharmacological properties of the substance in question, would constitute the culmination of an entirely new investigation, and thus be worthy of a form of protection which would encourage pharmacological research. Nevertheless, for reasons inherent in the practice of medicine, this solution had to be rejected as impracticable. Research aimed at finding new therapeutic applications was extremely intricate work, and its conclusions often illusory. Finally, the number of cases in which such patentability would be desirable, i.e. in which the same medicament could be given two entirely different therapeutic applications, was too limited for the advantages of the patentability solution to outweigh the practical disadvantages. It therefore proposed that methods for treatment by therapy be excluded from patentability.⁴²

The text of the Draft Convention of May 1972⁴³ made for the first time reference to what we now know to be the patentability of medical indication patents. The then art.50 stated that the following were excluded:

"methods for the 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 inventions having as their subject-matter substances or compounds, whether or not known, which are used for the first time for the purpose of practising such methods".

At the third meeting of the Co-ordinating Committee in June 1972,⁴⁴ proposals were made to amend the text of the May 1972 draft. No agreement was reached, however, on a new text and the issue was deferred. During the sixth meeting of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents in June 1972, the proposals were further discussed, and the proposal made by the German, UK, Danish, French and Netherlands delegations at the Co-ordinating Committee to introduce further changes to the envisaged provision relating to the patentability of pharmaceutical products was again discussed. The proposal suggested that products used in medical treatment methods should be patentable, even if they were known in the state of the art, provided that they were not known for use in ***213** any such medical treatment method.⁴⁵ The proposed amendment suggested deleting from art.50 the clause beginning with "this provision shall not apply" and adding to art.52 a new para.5 reading:

"Neither the provisions of this Article, nor those of Article 50, shall be interpreted as excluding the patentability of an invention consisting of a substance *per se* as a medicament provided that the state of the art does not include any such use of that substance."

In other words, the proposal wished to introduce first medical use protection for substances. Certain delegations, however, interpreted this proposal as introducing the patentability of not only the first medical indication, but also of further medical indications. The Conference noted that extending the provision as to including more than the first medical indication which was agreed upon in the previous compromise text would be a substantial modification of that compromise text and the proposal was deferred.

Interestingly, the proposal made at this meeting was also the first one aimed at introducing a specific provision covering medical indications and novelty. Prior to the 1972 draft texts, the only discussion took place at the level of the scope of the exclusion of medical treatment methods and the exception to that for products used in such methods. There was until 1972 no mention of any specific provision covering the exception to the rules of novelty which the patentability of medical indications patents would entail. Even though the discussions over the years had covered the issue as such, a text only materialised in 1972. The Draft Convention of December 1972 was the first one containing a provision on novelty in respect of medical indications claims. It read at that time:

"The provisions of paragraphs 1 to 4 shall not exclude the patentability of a substance or composition mentioned in Article 50, paragraph 3, even when the substance or composition in question is disclosed in the state of the art, provided that the state of the art does not include a disclosure of that substance for any method referred to in Article 50, paragraph 2(d)."⁴⁶

Upon a proposal from the Netherlands delegation,⁴⁷ the text of both the then art.50(3) and art.52(5) was proposed to be amended to how it read finally in the EPC 1973. Shortly after those meetings, the text materialised as we knew it in art.52(4) and 54(5) EPC 1973.

The early literature

The early literature discussed the patentability of both first and second medical indication inventions at length. Some wondered why such an exception was created in the first place, taking away the principle that all inventions in all areas of technology should be treated equally. The exception of the first medical indication in any event created an exception to this principle, and that was not supported by everyone.⁴⁸ It was argued during the Diplomatic Conference in defence of such an exception that without it there would be no adequate protection for pharmaceutical inventions.⁴⁹

But there was also a wider discussion regarding second and further medical indication patents. While some were of the view that it was clear that these further indications could not be patentable under the *214 EPC 1973,⁵⁰ they were not necessarily satisfied with what was in their view the clear will of the legislator. In the view of some, there was in fact quite often more reason to protect a second and further medical indication than the first one, the former being based on many years of specific research, while the latter with its broad wording and scope did not necessarily result from substantive research.⁵¹ Indeed, a specific feature of the first medical indication claim is that it is granted for *all* medical indications, while it does not necessarily disclose any one in particular, or maybe one in particular.⁵² In that line of reasoning, it was deplored that second and further medical indication patents did not seem to be patentable.

Others were of the opinion, however, that allowing second medical indication claims in the form of "use claims" (*Verwendungansprüche*),⁵³ which was conceived to be the only option in the early literature, would in fact protect the medical treatment, which was perceived as undesirable,⁵⁴ while still others were of the view that those use claims were the one and only solution to protect the second and further medical indication.⁵⁵ Indeed, the German Federal Supreme Court confirmed that use claims, i.e. use of a substance X for the treatment of disease Y, were acceptable under German law. One must be aware of the fact that, at that time, the German statute did not exclude medical treatment methods from patentability.⁵⁶ That was only put into effect by an amendment of the German Patents Act in 1981. Strangely enough, the German Federal Supreme Court has ruled that such a "use claim" is in fact comparable to a product claim, at least when it relates to a second medical use claim.⁵⁷ That made those claims allowable and not in conflict with the exclusion of medical treatment methods once these were introduced.

Opponents of second medical indication patents also used the argument that one cannot make new what is no longer new. If the substance is known in the state of the art, it cannot be "made" new by naming a new application. That was a view that was shared by some in the 1970s,⁵⁸ but was in fact somewhat in contradiction with what the EPC allowed already at that time under art.54(5) EPC, but which provision had admittedly not yet entered into force at the time of writing of some of these publications (the provision entered into force in 1978). Proponents of second medical indication patents on the other hand were of the conviction that not allowing such claims would be a hindrance for the pharmaceutical industry and for innovation.⁵⁹

Evaluation

Both the historical overview of the *travaux préparatoires* and the early literature do not give us a clear picture of the rationale of the patentability of further medical use claims. Even the patentability of the first medical use is to some extent somewhat clouded in a mist of conflicting views. One could derive from at least part of the *travaux préparatoires* that there were basically two camps. On the one hand, there were interest groups that were lobbying for a position where further medical applications of a known substance should be patentable. On the other hand, there seem to have been certain delegation members who were *215 quite reluctant to accept this, and believed that to the extent that it should be allowed, it should be confined to the first medical use of the known substance in a medical treatment. The present author must admit that the reasons for making such a limitation remain mysterious indeed. The *travaux préparatoires* do not shed a light on why the choice for limiting further medical applications of a known substance to the first was so made. It must be said that there is no immediate logic in making such a limitation. The Minutes of the Sixth Meeting

of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents in June 1972 discussed earlier clearly show that there was a difference in opinion between those who professed that there should be no limitation to the first medical use and those who advocated a limitation to the first medical use.

What emanates quite clearly from the *travaux préparatoires* is that the drafters of the EPC were quite occupied with preservation of the therapeutic freedom of medical professionals. There was a consensus that medical treatment methods should not be patentable. That to some extent also informed at least some of the opposition against medical indication patents, as it was doubted by some whether such patents would not interfere with the practice of physicians.

The case law after the entering into force of the EPC

The Enlarged Board of Appeal in the landmark G5/83 decision⁶⁰ could see no justification for limiting medical use applications of known substances to the first medical application. It did realise, however, that the text of the EPC 1973 did not allow such further medical indication, which it deemed acceptable, to be phrased as a purpose limited product claim, in view of the limitation in art.54(5) EPC 1973 to the first medical use:

"It should be added that the Enlarged Board does not deduce from the special provision of Article 54(5) EPC that there was any intention to exclude second (and further) medical indications from patent protection other than by a purpose-limited product claim. The rule of interpretation that if one thing is expressed the alternative is excluded (*expressio unius (est) exclusio alterius*), is a rule to be applied with very great caution as it can lead to injustice. No intention to exclude second (and further) medical indications generally from patent protection can be deduced from the terms of the European Patent Convention: not can it be deduced from the legislative history of the articles in question. On this last point, after conducting its own independent studies of the preparatory documents, the Enlarged Board finds itself also in accord with the conclusion of the Federal Court of Justice."⁶¹

It is also worth noting that, after the G5/83 decision by the EBA, the French Cour de cassation has allegedly held that second medical indication claims were not patentable.⁶² It must be said that, looking at the judgment, it is not immediately obvious that that court had meant to do that, but it has in wide circles been perceived as if it had done so.

The solution provided by the EBA in the G5/83 case has for some time remained somewhat controversial in the courts of several Member States, including Germany, the UK, the Netherlands and Sweden.⁶³

Also the German Federal Supreme Court could read no prohibition of further medical indication claims from being patentable⁶⁴: *216

"What it does show however are the efforts of the Government delegations to provide for appropriate protection, seen at the time as product protection limited to the first therapeutic use of a known substance. The exclusion of such product protection limited to the specific use where a further medical use is found is thus no indication of protection also being excluded for a use invention involving the provision of a substance formulated for treatment by therapy and its use to treat an illness for which it has not previously been used. Although when the provisions in question were drafted arguments against protecting use inventions of this kind may have been voiced, this Court cannot state with certainty that the Contracting States concurred in wishing to exclude protection for use inventions of this kind by means of the provisions ultimately adopted in Article 52 (4) and 54 (5) EPC. On the contrary, the majority of Working Party I unambiguously stated in BR/177/72 of 13 April 1972 that there should be no explicit exclusion of such protection. This statement was never unambiguously and unanimously retracted during the subsequent negotiations. Although some participants at the Munich Conference have since expressed the view in the literature that Article 52 (4) and 54 (5) EPC as a whole exclude

protection of use inventions of this kind,⁶⁵ these personal comments by Conference participants do not convince this Court that the Contracting States as a whole intended to exclude these use inventions from patentability."⁶⁶

This confirms what I said earlier, that it is difficult to determine the exact will of the legislature regarding patenting further medical indications in the *travaux préparatoires*.

The court then continued by holding that there are no other objections to be seen in preventing further medical indications claims (which under German law can be framed as use claims for the treatment of a medical indication) from being patentable:

"Neither ethical nor legal policy considerations stand in the way of protection for use inventions involving the provision and application of formulated chemical substances in the treatment of the human body by therapy ... After the lifting of the 'patentability prohibition' on pharmaceuticals in the Federal Republic of Germany, socio-ethical reservations concerning patent protection for pharmaceuticals ceased to apply here. Nonetheless, in the decision referred to above, which concerned a method for cosmetic surgery to prevent baldness, this Court broached the question of whether socio-ethical considerations justified the exclusion from patentability of methods for healing the human body, but did not go into it further ... In the subsequent decisions, which concerned the patentability of the use of substances for treatment by therapy of the human body (9 IIC IIC Jahr 1978 Seite 42 (1978)—Benzolsulfonylharnstoff, and 14 IIC IIC Jahr 1983 Seite 283 (1983)—Sitosterylglycoside), it affirmed their susceptibility of industrial application and did not return to consideration of whether such methods might be excluded from patentability on socio-ethical grounds. Nor could such grounds have carried any weight. Those provisions of the Patent Law governing the exclusion of inventions which if published or used would be contrary to public order or morality, namely in Section 2, point 1, first clause, of the Patent Law (see also Article 53 (a) EPC), make no mention of treatment of the human body by therapy. The teaching that sufferers may be cured of an illness if treated with a particular substance is in full accord with the dictates of morality, promoting the public weal, not its woe. Nor does the grant of an exclusive right for a limited period of time in respect of such teaching, to reward the inventor for disclosing it, attach any stigma of immorality, contrary to views sometimes expressed. It is also reconcilable with public order. The doctor's freedom of prescription is limited by patent protection for use inventions no more and no *217 less than by protection for product claims for pharmaceuticals or product claims limited to the application of known products for first medical use. The fear that protection of substances by product claims, whether unlimited or limited to a specific use, could be unduly extended through subsequent grant of use claims to treat further illnesses is groundless given that such use inventions remain subject to general patentability criteria, notably inventive step. The same is true of concern that the rights of the proprietors of product patents for the substances to be provided and used under the invention might be eroded. There is no evidence that health care could be adversely affected if such inventions were patentable. On the contrary, the likely outcome would be to encourage pharmaceutical research, to the benefit of all."⁶⁷

When the German Federal Supreme Court and the EBA decided that there was no clear rationale in the EPC to exclude further medical indication patents, they were probably stretching the will of the drafters of the EPC, as they clearly limited patentability to the first medical indication, but it must be admitted that the discussions during the negotiations at least showed that there were conflicting views on the issue. The legalistic "escape route" which both the German Federal Supreme Court in its case law and the EBA in the G5/83 case took by holding that only product claims were not possible for further medical use claims is from a purely formal legal point of view correct, but their patentability does not at such stand out from the EPC drafting documentation. On the other hand, logic also plays a role. The drafters of the EPC have remained rather silent on the exact reasons why further medical indications should not be patentable. There is no apparent logic in allowing the one but not the other.

In the UK, the patentability of second and further medical indications has also not been without its problems. Even though the Swiss claims formula in the *Eisai* case was relatively early accepted by the UK courts,⁶⁸ later cases have

struggled to determine whether such a further medical indication claim was in fact not covering the medical treatment. A case at point here is [Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc](#),⁶⁹ where it was held:

"In my view the form of claim 1 does not disguise its effect. The invention was the discovery that by changing the treatment from a 24 hour infusion to 3 hours a similar effect was obtained with less neutropenia. That was a discovery that a change in the method of treatment provided the result. The claim is an unsuccessful attempt to monopolise the new method of treatment by drafting it along the lines of the Swiss-type claim. When analysed it is directed step-by-step to the treatment. The premedication is chosen by the doctor, and administered prior to the taxol according to the directions of the doctor. The amount of taxol is selected by the doctor as is the time of administration. The actual medicament that is said to be suitable for treatment is produced in the patient under supervision of the medical team. It is not part of a manufacture. In my view Mr Thorley is correct. The invention made and claimed was a method of treatment precluded from patentability by [section 4\(2\)](#) (Article 52(4))."

In [Actavis v Merck](#), Jacob LJ held that in the aforementioned [BMS](#) case, the judge came to that conclusion on a very narrow point, i.e. that the specific claim was in fact trying to claim the medical treatment, and did not read a wider rejection of further medical indication claims as covering medical treatments in principle.⁷⁰

Interestingly, the EBA admitted in the G2/08 case that the Swiss claim is inherently difficult to uphold:

"Moreover, Swiss-type claims could be (and have been) considered objectionable as regards the question as to whether they fulfill the patentability requirements, due to the absence of any functional ***218** relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process. Therefore, where the subject matter of a claim is rendered novel only by a new therapeutic use of a medicament, such claim may no longer have the format of a so called Swiss-type claim as instituted by decision G5/83."⁷¹

Whatever one can make of all of the above, the new EPC 2000 has introduced, also with a view to avoid any further confusion within the Member States, a clear rule regarding second and further medical use claims, which are now protected as purpose limited product claims (see art.54(5) EPC).⁷²

Relationship between non-patentability of medical treatment methods and patentability of medical indication claims

Even though the patent system may have wished to ensure therapeutic freedom by excluding medical treatment methods from patentability, it must be admitted that it has to some extent deviated from that principle by allowing patent protection for the products used in those therapies or medical treatments. Admittedly, the access to certain drugs for physicians will have an influence on the therapy chosen. That is true, and it uncovers at the same time a thorny question, which is to what extent should inventions relating to healthcare be patented or not? It is not very difficult to use very similar arguments against patenting medical treatment methods and the products, i.e. drugs and medical instruments and devices, used in those methods. The Australian Federal Court referred in the [Bristol Myers Squibb v Faulding](#) case in that connection to "the insurmountable problem, from a public policy viewpoint, of drawing a logical distinction which would justify allowing patentability for a product for treating the human body, but deny patentability for a method of treatment".⁷³ This is not the place to deal with all the parameters of this important question,⁷⁴ but suffice to say that it was considered that the huge investment in developing drugs should be rewarded as it benefits healthcare, while this would not be so guaranteed if medical procedures were patent protected, as they might not be accessible to physicians. The argument goes that pharmaceutical companies have an interest in making their drugs available to patients, there are quite often substitutes available creating more competition and hence a higher interest in providing access to the drugs the pharmaceutical companies develop/produce,⁷⁵ and there is still a difference between patenting a drug and patenting

the very methods of medical treatment, which hits at the core of the physician. There will always be a tension between the fundamental right to health and the privatisation of rights to drugs and/or methods used in providing health, but it would lead us too far to go into the discussion of this at first glance difficult relationship between fundamental rights and intellectual property rights.⁷⁶

It is also undeniable that patents for drugs, second medical indications and medical devices have an influence on the therapy prescribed by the physician. That will for instance clearly be the case if a medical instrument or medical device such as a stent has been patented and the physician has to make a choice not to insert a specific stent into a patient's body (which stent is allegedly the best possible treatment for that specific patient) because it would be too expensive for the healthcare system to do so. It is true that for medical devices, but for that matter also for medicines, physicians cannot always prescribe the optimal remedy, because it is unavailable for reimbursement in a particular healthcare system. To that extent, the ***219** patent system interferes directly with medical treatment decisions.⁷⁷ That is undeniably true, but I think there is still a difference between choices which the medical profession needs to take because of budget constraints within the healthcare system, and the risk which a healthcare professional runs of committing a patent infringement in the normal course of his/her work.

Jacob J (as he then was) pointed in the **BMS** case to the limited scope of the medical treatment exclusion:

"There is also the limited purpose of the exception to be considered. It is not so broad as to stop doctors using whatever they feel they need to treat patients. If that were the purpose then one would not allow patents for medicines or medical implements at all. The purpose of the limitation is much narrower, merely to keep patent law from interfering directly with what the doctor actually does to the patient. Patent monopolies are permitted to control what he administers to, or the implements he uses on, the patient. The thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment. It is noteworthy that in the US any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble."⁷⁸

The somewhat difficult relationship between the non-patentability of medical treatment methods and the patentability of medical indications was also eloquently worded by the Appeal Court in the same **BMS** case:

"Art.52(4) was not intended to exclude pharmaceutical preparations from being patentable. That has the result that restrictions can be imposed by patentees upon treatment. The section has the limited purpose of ensuring that the actual use, by practitioners, of methods of medical treatment when treating patients should not be subject to restraint or restriction by patent monopolies. The difficulty is to decide whether the restraint concerns a method of treatment as opposed to what is available for treatment."⁷⁹

In conclusion, further medical indication patents seem to sit very close to the therapy which a physician wishes to prescribe. In some cases, the medical indication so patented is a new dosage, or the fact that a new patient population can now also be treated with an existing drug.⁸⁰ And with the advent of the new EPC 2000 purpose limited product claim, this could be seen to become even worse.

Some specific problems relating to medical indication claims

Introduction

In this section we will discuss two types of further medical indications patents which are not only very relevant for the discussion we have in this contribution, but which present specific problems which deserve a closer look. Those two "embodiments" are patents for new sub-populations and patents for dosage regimes. ***220**

New sub-populations

Specific for personalised medicine might be the case that the drug is not new and it is already known for the treatment of the condition claimed. What is in fact invented is the use of a known drug for the treatment of a known condition for a new patient sub-population which is defined by the identification in such patent sub-population of a new biomarker.⁸¹ As we have seen earlier, under the EPC and EPO case law, a variety of second and further medical indication claims is considered to be patentable. Most common types are those inventions relating to a novel group of subjects,⁸² relating to a new route or mode of administration,⁸³ relating to a different technical effect and leading to a truly new application,⁸⁴ and those relating to a new dosage regime for an existing drug.⁸⁵

For the present type of invention, the only novel feature is the identification and treatment of a new patient sub-population.

From a patent law perspective, there are at first sight a number of problems with such patents. The prior art will already include the new sub-population, as this sub-population is part of the larger patient population which was already treated with the known drug before (be it perhaps in a different dosage). The biomarker on the basis of which the sub-population is identified is arguably also not new, as it was always present in the population (of which the sub-population forms part) for which the drug was already patented/used.

There has been an evolution in the case law of the EPO relating to sub-populations. The earlier case law relating to second and further medical indications claims did recognise novelty of a new sub-population.⁸⁶ However, in case T233/96,⁸⁷ the Technical Board of Appeal held that if

"the use of a compound was known in the treatment or diagnosis of a disease of a particular group of subjects, the treatment or diagnosis of the same disease with the same compound could nevertheless represent a novel therapeutic or diagnostic application, provided that it is carried out on *a new group of subjects which is distinguished from the former by its physiological or pathological status* (T19/86, T893/90). This does not apply, however *if the group chosen overlaps with the group previously treated* or the choice of the novel group is arbitrary which means that no functional relationship does exist between the particular physiological or pathological status of this group of subjects (here humans who are unable to exercise adequately) and the therapeutic or pharmacological effect achieved".⁸⁸

In other words, and applied to the present subject of personalised medicine, if the sub-population identified overlaps with the group previously treated, there is no novelty. In the case of personalised medicine, the previous treatment will always have covered the entire patient population, and the now identified ***221** subpopulation which is susceptible to the newly claimed treatment will in that sense always overlap with the patient population already identified and treated before.

More recent case law has condemned that case⁸⁹ and has held that there is no basis in both aforementioned cases to support the interpretation given in the T233/96 case. In T1399/04,⁹⁰ the Board held in particular that "The present Board does not see a basis for this interpretation in the relevant parts of decisions T19/86 (points (5) to (8)) and T 893/90 (points (4.2) to (4.6))".⁹¹

The standard for evaluating whether a sub-population can be considered novel over the prior art and hence constitute the basis for a further medical indication claim is, according to at least some of the recent case law, the following:

"If the use of a compound was known in the treatment or diagnosis of a disease of a particular group of subjects, the treatment or diagnosis of the same disease with the same compound could nevertheless represent a novel therapeutic or diagnostic application, provided that it is carried out on a new group of subjects *which is distinguished from the former by its physiological or pathological status* (cf. decisions T19/86, [1989] OJ EPO 24; point (8) of the reasons and decision T893/90 of 22 July 1993 (point (4.2) of the reasons))." ⁹²

A recent case supports the stance taken by the Board in the T1399/04 case, which consequently creates some confidence that the way taken in the earliest case law and confirmed in T1399/04 and the present recent case is probably the state of the law at the EPO. In T734/12, ⁹³ the Board held that

"According to the established case law of the Boards of Appeal, the use of the same compound in the treatment of the same disease for a particular group of subjects, could nevertheless represent a novel therapeutic application, provided that it is carried out on a new group of subjects which is distinguished from the former by its physiological or pathological status" ⁹⁴

In other words, a new group of subjects which is distinguished from the former by its physiological or pathological status can constitute novelty and hence can become patentable. Typically, a sub-population can distinguish itself from a population from which it forms part generically for instance by not reacting to a specific drug in a dosage or administration already part of the state of the art or by showing a high degree of adverse side effects or even toxicity of the drug administered to that sub-population. That sub-population might also distinguish itself because the medical condition for which it is treated is caused by a specific genotype or a specific mutation, which might make the standard treatment known in the state of the art ineffective. These would all be biomarkers, and the patented invention has established a correlation between the known drug and those previously unknown biomarkers. As there is, in line with the EPO case law discussed, still room for at least a claim or novelty based on a further medical indication, research into specific sub-populations might be rewarded with patent protection.

Even though the matter now seems to be resolved at the EPO level, the same cannot be said of the national level. UK case law has conformed itself to the case law of the EPO when it comes to further medical indication claims, be it with some problems, as we have seen. However, despite the fact that there is at least coherence between the UK and the EPO regarding further medical indication case law and hence also at first sight the patentability of patent claims defining the treatment of sub-populations, there is another concept in patent law that has put a spanner in the patent works. In the UK, for instance, the concept of what is inherently disclosed in the prior art could potentially present problems for the ***222** patentability of a second medical indication claim for a new sub-population, where such a sub-population would already have been inherently included in the population for which the molecule was already known in the state of the art. Even some recent case law seems to point to this problem.

The concept of what is inherently disclosed in the prior art is one that plays a role in the determination of novelty, and basically answers the question whether a feature that was inherently present in the prior art, for instance in an effect already achieved by a process or product in the prior art, without that effect being known to take place in the prior art, can later be patented, or whether it is anticipated as being already disclosed in the prior art, and hence no longer novel. It can immediately be seen that the concept is relevant in the context of personalised medicine. Claiming a medical indication, for instance the identification of a new sub-population, can present problems, as that sub-population has already been inherently included in the population for which the molecule had already been disclosed in the prior art.

As far as the EPO is concerned, the concept has been dealt with in G2/88, where the Enlarged Board of Appeal held first that

"the Enlarged Board would emphasise that under Article 54(2) EPC the question to be decided is what has been 'made available' to the public: the question is not what may have been 'inherent' in what was made available (by a prior written description, or in what has previously been used (prior use), for example). Under the EPC, a hidden or secret use, because it has not been made available to the public, is not a ground of objection to [the] validity of a European patent".⁹⁵

It then concluded that

"the answer to question (iii) may therefore be summarised as follows: with respect to a claim to a new use of a known compound, such new use may reflect a newly discovered technical effect described in the patent. The attaining of such a technical effect should then be considered as a functional technical feature of the claim (e.g. the achievement in a particular context of that technical effect). If that technical feature has not been previously made available to the public by any of the means as set out in Article 54(2) EPC, then the claimed invention is novel, even though such technical effect may have inherently taken place in the course of carrying out what has previously been made available to the public".⁹⁶

Applied to our sub-population example, the identification of a new sub-population would be novel, even though already inherently present in the prior art, as long as that new technical feature, i.e. the identification of the new sub-population, had not been previously disclosed to the public.

Under UK case law, the situation is in our view different. In the [Merrell Dow v Norton](#) case, the House of Lords held that there was anticipation if the inevitable result of following the instructions of a prior art document, or patent for that matter, was that the technical feature which is claimed later would be arrived at.⁹⁷ In the case at hand, the invention related to an acid metabolite of terfenadine, the latter being known in the prior art. According to the House of Lords, applying the teaching of the terfenadine patent would have led to the production of the acid metabolite in the human body, and hence, even though at the time of the terfenadine patent one may not have known that such took place, a later patent application for the acid metabolite would lack novelty over the prior art terfenadine teaching. Applying this to personalised medicine and the invention identifying a sub-population, as the effect claimed in the sub-population would already have been present in any invention covering a patient population of which the sub-population forms part, one could argue that an invention relating to a sub-population may lack novelty over the prior art. *223

Dosage regime patents—a controversial issue

A type of invention which is likely to be of major importance in the context of personalised medicine is the dosage regime patent. Owing to the presence of certain biomarkers in certain patients, the standard treatment could be shown to be ineffective. That could imply that, in certain cases, an alternative drug will need to be administered, in which case we are in the situation of a further medical use where an existing drug is used to treat a new group of patients. In a second possibility, the solution could be found in administering a different dosage to the group of patients with the specified biomarker. In that case, the relevance of dosage regime patents becomes crucial.

For many years, case law has discussed the question whether a new dosage regime can be protected as a further medical indication of an existing drug or whether it is instead nothing more than a medical treatment method.

From a legalistic point of view, the question is relatively easy to answer. A claim drafted in the Swiss claim format claiming the use of a substance for the manufacture of a medicament for the use in the treatment of a disease for administration in a certain dosage, or in the new EPC purpose limited product format claiming the substance for the use in the treatment of a disease for administration in a certain dosage, are as such perfectly patentable claims, as they are not claimed as medical treatment methods. As the UK court said in the [Actavis](#) case,

"making up the substance for administration is not in itself administration — is not treatment. That would seem to be the case whether the substance is made up in a factory (here 1mg. pills of finasteride) or in a pharmacy (where it may even be patient specific)".⁹⁸

Whether they fulfil the novelty and inventive step requirements is quite often in practice a different matter, but that is a decision taken on the individual facts of the case. In other words, a legalistic approach would see no conflict between dosage regime patents, which protect the making up of the substance, and the non-patentability of the medical treatment, which protects the treatment as such, admittedly with the aid of the pills so made up.

The question is whether it is not in practical effect a medical treatment in disguise. That was the view of the UK court in [Bristol-Myers Squibb v Baker Norton](#),⁹⁹ where it was held that

"in my view the form of claim 1 does not disguise its effect. The invention was the discovery that by changing the treatment from a 24 hour infusion to 3 hours a similar effect was obtained with less neutropenia. That was a discovery that a change in the method of treatment provided the result. The claim is an unsuccessful attempt to monopolise the new method of treatment by drafting it along the lines of the Swiss-type claim. When analysed it is directed step-by-step to the treatment. The premedication is chosen by the doctor, and administered prior to the taxol according to the directions of the doctor. The amount of taxol is selected by the doctor as is the time of administration. The actual medicament that is said to be suitable for treatment is produced in the patient under supervision of the medical team. It is not part of a manufacture. In my view Mr Thorley is correct. The invention made and claimed was a method of treatment precluded from patentability by [section 4\(2\)](#) (Article 52(4))."

Another interesting case is the so-called alendronate case in the UK.¹⁰⁰ The patent related to a dosage regimen relating to the active ingredient alendronate, and more in particular claimed a dosage regimen of *224 a 70mg once weekly dosage, while the prior art already comprised a 10mg daily dosage regimen.¹⁰¹ In first instance, Jacob J (as he then was) was inclined to rule that it was not a medical treatment method, but felt himself bound by [Bristol-Myers Squibb v Baker Norton](#):

"But for the decision in [Bristol-Myers Squibb v Baker Norton \[2001\] R.P.C. 1](#) I would have held not, despite the width of the claim. The monopoly covers the preparation of the dose to be administered but not its actual administration. It is true that that might catch a doctor or nurse who measured out the dose prior to administration, but that would be an act of preparation not administration. However the principle decided by Bristol-Myers binds me."¹⁰²

Jacob J did so with regret:

"I conclude that the claim is in substance to a method of treatment of the human body by therapy. I do so with regret. For patents are provided to encourage research. If new and non-obvious improved methods of administration of known drugs for known diseases are not patentable in principle—even with a Swiss form claim, then there will be less of a research incentive to find such methods. Giving the exception a very narrow scope, so that any preparation used in such a method is protectable if only by the artificial construct of a Swiss form claim, would be a research incentive. But I must follow the current state of interpretation of the exception in [Bristol-Myers](#)."¹⁰³

In 2008, Jacob LJ took the opportunity in the [Actavis v Merck](#) case to rule that the rationale in the [Bristol-Myers](#) case was based on a very narrow point only:

"So Aldous L.J. decided the method of treatment point on a very narrow ground indeed. It was that if in essence the claim is merely to a method of treatment it is bad. The claim in the present case is far from that. It is in its essence directed at the manufacturer. The doctor's only involvement will be in prescribing for the treatment of *aa* [Androgenic alopecia]

the 1 mg pill made by an alleged infringer. We do not regard Aldous L.J.'s ratio as binding in its effect so far as the general case of dosage specific Swiss form claims or so far as this case is concerned." ¹⁰⁴

As we know from the **BMS** case, the patent required the permanent involvement of the physician in carrying out the claim. Jacob LJ was of the view that a "normal" dosage regime claim would only require the involvement of the physician in the prescription stage, but not during the treatment itself.

Under German law, a dosage regime claim would be patentable as long as it is formulated as "formulated for administration":

"However, there are no reservations against the admissibility of the patent claims according to subsidiary motion 2, which provides under both patent claims that the medication containing carvedilol is formulated in certain doses for administration over certain periods. Accordingly, protection is to be accorded to the use of a chemical substance in the therapeutic treatment of the human body, such substance being formulated to suit such use for instance, by means of suitable packaging for the tablet sizes, an inscription on the package or package inserts. Pursuant to this Court's case law, such use of a chemical substance is not excluded from patent protection under Sec. 5(1) German Patent Act (basically, BGHZ 88, 209, 215 Hydroxydipyrindin). For Art. 52(4) EPC, which corresponds verbatim with Sec. 5(2)(1) German Patent Act, the same is true. The patent claims of subsidiary motion 2 are ***225** not opposed by the ineligibility for patent protection of procedures for the surgical and therapeutic treatment of humans or animals." ¹⁰⁵

If the claim would read "for administration", it would be seen as a medical treatment claim, and hence be non-patentable:

"Administering a medication intended for the treatment of a particular condition amounts to a therapeutic procedure for the treatment of the human body. It is not an element of substance formulation in the treatment of illnesses (departure from BGHZ 88, 209, 217 — Hydroxydipyrindin) but follows same. Determining a suitable therapy plan for a patient, including drug prescriptions and dosage, is a characteristic part of the activities of the treating physician and, as such, excluded from patent protection under Art. 52(4) European Patent Convention (EPC) and Sec. 5(2) German Patent Act. And while a claim as to use may also pertain to the formulation of a certain agent in the treatment of a condition, which occurs on the basis of package inserts or instructions on the package, the mere dosage recommendations, as detached from formulation, do not automatically come into patent protection as a result. Insofar as the Federal Patent Court, as part of its more recent practice, holds a different view on this matter, such position cannot be seconded. Any other result could not be reconciled with the wording of Art. 52(4) EPC and would deprive such provision of a material portion of the scope of application assigned to it." ¹⁰⁶

This case was later confirmed and recently also in the German Warner Lambert case. ¹⁰⁷

The EBA held in the G2/08 decision that dosage regime claims are patentable if formulated in the appropriate claim format. Admitting that there is a very thin line between non-patentable medical treatment methods and the patentable products used in those methods, the EBA took the view that a strict distinction needs to be made between methods for treatment and the products claimed for use in those methods, as art.53(c) EPC 2000 provides, otherwise the provision would be without meaning:

"*De facto* the two concepts of a method for treatment by therapy and of a product to be used in such a method are so close to each other, that there is a considerable risk of confusion between them unless each is confined to its own domain as allocated to it by the law. In this respect it would be improper to consider the second sentence of Article 53(c) EPC as a *lex specialis* to be interpreted narrowly, rather on the contrary it is appropriate to give both provisions the same weight, and draw the general conclusion that in respect of claims directed to therapy, method claims are absolutely forbidden in

order to leave the physician free to act unfettered, whereas product claims are allowable provided their subject-matter be new and inventive." ¹⁰⁸

The EBA then continued by holding that art.54(5) EPC 2000, which covered further medical indication patents, does not specify which specific uses can be patentable, leading to the conclusion that there is no limitation to that effect:

"Article 54(5) EPC does not define the nature of the further therapeutic use of a substance or composition already known as a medicine deserving protection under Article 54(5) EPC further than by saying that it must be specific. In particular, it does not define any degree of distinctiveness the new use would be required to have in order to qualify as a specific use within the meaning of that article. On the contrary, the wording of the provision stipulates that 'any' specific use not comprised in the state of the art may be eligible for patent protection under that article. *226 " ¹⁰⁹

The Board then further held that nothing in the provision would lead to an interpretation that it only aimed to cover claims protecting the use in the treatment of a different disease, ¹¹⁰ and concluded:

"The Enlarged Board comes to the conclusion that there can be only one sensible way of construing the requirement underlying the specificity of the use, namely merely by contrast to the generic broad protection conferred by the first claimed medical application of a substance or composition, which is in principle not confined to a particular indication. Thus, the new use within the meaning of Article 54(5) EPC need not be the treatment of another disease." ¹¹¹

The Board further emphasised that there was already a large body of case law relating to further medical indication which was not confined to a specific disease, ¹¹² and that there was nothing to be found in the *travaux préparatoires* of the EPC 2000 (where it was expressly provided in the statute) that second medical indication patents would have to be limited to those inventions only which claimed use in the treatment of a new condition, nor in the decision of the EBA in G5/83 to that effect. ¹¹³

Dosage regimen patents are probably a very good example of the tension between non-patentable medical treatment methods and patentable medical indication claims. This is best exemplified by the UK case law, which is to some extent conflicting on the issue. And even the G2/08 decision admits that both concepts are so closely related that is easy to be confused. This is not helped by the fact that there is a rather unclear rationale for excluding medical treatment methods from patentability, and an equally unclear rationale for allowing patent protection for medical indications. Indeed, the historical overview given earlier shows that the legislature was to some extent concerned that allowing medical indication patents would in fact hollow out the exclusion of medical treatment methods from patentability. It took cold economic arguments to convince the legislature to allow patent protection for medical indications. I am not sure that, if the legislature had had the knowledge we have today of the use of medical indication patents, it would have concluded in favour of patentability.

Conclusion and suggestions

This contribution demonstrates that medical indication patents and the exclusion from patentability of medical treatment methods have a somewhat complex history and rationale. Historically, medical treatment methods have been excluded from patentability without a very clear and uniform reason for doing so, and in fact the rationale has changed over time. That shows that it is not an exclusion with sound roots. That is exacerbated by the fact that in other parts of the world, e.g. the US, medical treatment methods are deemed patentable.

Having to deal with an exclusion that has no sound rationale is one thing, but matters become even more complicated if certain types of patents, i.e. medical indication patents, come to sit very close to such medical treatment methods. A

legal technical argument that a medical indication patent is protecting the (making of the) product for the treatment of a certain condition and not the activity of treatment by the physician itself is only partly helpful. Such arguments are helpful in the context of a court case where the latter is called to apply the law. They provide a less satisfactory solution in a policy context.

In my view, certain medical indication patents come very close to the clinical activity of the physician, e.g. the decision to use a specific dosage to treat a disease. One could argue that this is not different from ²²⁷ any other prescription. Indeed, the physician will often prescribe a drug in a certain—quite often standard—dosage. The fact of the matter is, however, that in the "standard" case, the patent covers the molecule as such, irrespective of the dosage, and the physician is prescribing a patented medicament. In the case of a dosage regime patent, the patent covers the product to the extent that it is used for the treatment with a specific dosage. That is exactly what the physician is going to do. This leads to the conclusion that there is a distinction to be made between the standard treatment and the dosage regime patent. But it must also be admitted that a dosage regime patent does not necessarily differ very much from a case where a patent covers the drug for the use in the treatment of a specific medical condition. Also in this case, the physician will prescribe the medicament for use in the treatment of that condition, while the drug is already known to be used for treating other conditions. There is probably not a fundamental difference between the two. And the honest answer is also that the issue remains the subject of controversy.

What it all reveals, however, is that patents have come very close to what the clinician is effectively doing as part of his medical treatment, and in that sense medical indication patents have become somewhat worrisome. Those worries will only grow when the reader studies the analysis we have been making regarding patent infringement of medical indication patents in the previous issue of this Journal, which demonstrates that the clinician faces a real-life risk of patent infringement by prescribing a patented dosage for an as such non-patented medicinal product.

The question is now how to deal with this conundrum. On the one hand there is a rationale that patents should not be granted which interfere in a certain way with the clinician's activities. I say in a certain way, as the legislature could not have meant to exclude all those inventions from patentability which interfere with the activities of the clinician, witness the fact that patents are allowed for products used in such activities which to some extent also interfere with the activities of the clinician. On the other hand, there was the clear intention of the legislature to allow patents not only for new chemical molecules, but also for a further medical use of already existing molecules. Such further medical use can consist in the use of the molecule for the treatment of a different medical condition, a new mode of administration, a new dosage regime, etc.

This leads to the question of whether the exclusion from patentability of medical treatment methods in today's complex medical and pharmaceutical landscape still makes sense. Alternatively, one can also wonder whether, on the contrary, the patentability of medical uses has been derailed to the extent that it in fact tries to cover the activities that would normally be saved for the clinician by the exclusion of medical treatment methods from patentability.

In what follows, with a view to presenting solutions to the present unsatisfactory state of the affairs, I will evaluate two major options in respect of medical treatment methods and medical indication patents, i.e. abolishing the exclusion from patentability of medical treatment methods and/or abolishing medical indication patents.

Abolishing the exclusion for medical treatment methods (and abolishing medical indication patents)

A first option could indeed be to abolish the exclusion from patentability of medical treatment methods. As we have demonstrated in this contribution, the rationale for having the exclusion is indeed not at all solid. The idea that health should be protected is obviously a rationale that everyone would support, but starting from such a premise makes it difficult to argue why it should only apply to medical treatment methods and not, for instance, also to pharmaceuticals,

medical indications patents and medical devices. Case law has also questioned the logic of the exclusion. Whitford J held in [Schering AG's Application](#):

"Although it is difficult to see any logical justification for the practice in relation to processes for medical treatment, if the object of the system is in truth to give hope of a reward to people whose *228 research and industry results in valuable products or processes, it does appear that in 1919 and again in 1949 Parliament must have proceeded upon the assumption that patents for processes of medical treatment as such were not within the contemplation of the statute." ¹¹⁴

Jacob J held in the [BMS](#) case that

"the thinking behind the exception is not particularly rational: if one accepts that a patent monopoly is a fair price to pay for the extra research incentive, then there is no reason to suppose that that would not apply also to methods of treatment. It is noteworthy that in the US any such exception has gone, and yet no-one, so far as I know, suggests that its removal has caused any trouble". ¹¹⁵

In other words, absent a clearly defined foundation for not allowing medical treatments to be patentable, why not just allow patent protection for them?

If combined with abolishing medical indication claims (which for instance do not exist in the US), it would first of all do away with the relatively difficult interpretation of further medical indication claims, and it would bring the invention down to what one has tried to achieve in the first instance. It would also make an end to the not always very clear distinction between the provision of drugs for a very specific medical treatment which is claimed and the medical treatment itself. It would in other words be likely to provide more legal certainty for all of society and all of its players. Allowing medical treatment claims would also present no problem with the TRIPS Agreement in such a scenario; to the contrary, as art.27 TRIPS lays down the principle that inventions in all areas of technology should be patentable. Provided that there were a therapeutic freedom exception, ¹¹⁶ clinicians would also be free from liability claims.

What are the drawbacks? One of the main drawbacks is obviously the concern that medical professionals would be hindered by those patents. That does not necessarily need to be the case, provided that additional measures are introduced into the patent system. One of them would in any case need to be a therapeutic freedom exception, i.e. that clinicians would be allowed to use the patented invention without committing an infringement, or at least without being held liable for it.

But that may not be enough. As has been suggested in the literature, the mere fact that there is a patent on a medical treatment method could as such have a negative effect, as it may already cause a lack of access to the invention owing to practices of patent holders. Ventose has called this the question of control. ¹¹⁷ While a pharmaceutical company can control access to the drugs by raising prices or volumes, such a company has inherently always an interest in selling products, which means it is unlikely that it would lead to a non-supply. In the view of Ventose, the situation would be different for medical treatment methods, as this would constitute a different demand-supply situation. The method would be controlled by the physician-patent holder, and other physicians would have no access to it without a licence. I am not sure that is entirely true, as the patented method will be publicly available in the patent specification, and any physician could hence apply the method, even absent a licence. The latter practice would expose the physician to an infringement claim, but that is why it is important that also in this scenario there would be a therapeutic freedom exception.

Furthermore, it might be difficult to accept that medical treatment methods could be patentable for public (health) policy and socio-ethical reasons. ¹¹⁸ Over the course of time, legislatures and courts have come to hold that medical treatment methods should not be patentable in the interest of the protection of health. It is very difficult to see how this could be overturned easily. Furthermore, the right to health as a *229 fundamental right has entered an era of growing exposure

to a variety of debilitating diseases that are more and more centre stage, even though admittedly it is debatable as to whether it is a primary and inalienable right that can and should be enforced at the same level as other fundamental rights such as the right to life, freedom of expression, etc.¹¹⁹ With a growing concern about our health and access to healthcare, the suggestion of allowing patents for medical treatment methods is likely to be a long and heavily debated process. Or as the Federal Court of Australia put it in *Bristol Myers Squibb v Faulding*:

"Perhaps the most powerful argument against patenting is the idea that a patient may be denied medical treatment that she needs. It is certainly the most emotive of the arguments. It presumes that a medical practitioner may be unable to obtain the right to use a particular process, or may not be able to do so within due time, and therefore will be unwilling to undertake the process on her patients for fear of legal action."¹²⁰

Another aspect is of course that a patent on a medical treatment method is capable of affecting the physician directly in his daily activities, more than could possibly be the case with the patentability of drugs. That is largely true, but not entirely, as the case law relating to medical indications patents demonstrates, where the physician is also at risk of committing a direct infringement.

In effect, allowing medical treatment methods to be patentable would have some benefits, but in view of the multiple objections from a public (health) policy and socio-ethical point of view, added to the fact that it does not in effect create that much more legal certainty, means that it is not an ideal candidate for a good solution.

Abolishing medical indication patents

Another option could be to abolish medical indication patents altogether. A rationale for doing so could be that the *travaux préparatoires* tell us that allowing patents for medical indications was not a "love at first sight" situation in any case, and there is evidence that, as from the very early days, there was a concern that it might affect the activities of the clinician in a negative manner.

Secondly, not only is there a historical reason to do so, the problems which medical indication patents presently cause to a variety of players in the medical care chain¹²¹ could also be seen as a good reason to do away with medical indication claims.

Thirdly, since the EC pharmaceutical inquiry,¹²² there seems to be at least some anecdotal evidence that medical indication claims are used as an evergreening tool, i.e. a tool to extend in a number of ways patent protection for a molecule that is no longer patent protected as such.

However, for a multiplicity of reasons this is quite unlikely to become reality at least in the short to mid term. The pharmaceutical industry has striven for many years to obtain this form of protection, and it is unlikely that a legislature would have the courage to do away with it. This is even less likely in the context of current trends in personalised medicine, where the relevance and importance of medical indication research and patents seem to grow exponentially. In other words, the era of personalised medicine has made medical indication patents one of the most attractive forms of patent protection, which means that it is highly unlikely that the pharmaceutical industry (including the biotechnology industry) will not do whatever it can do to preserve this form of patent protection. *230

I am also not convinced that this would be an optimal solution. There are plenty of examples where further medical indication patents have proven to be quite important innovations which benefited healthcare (think of patients who could previously not be effectively treated for their condition and find themselves after many years of research into the various possibilities suddenly in a situation where a drug that was not originally designed for treating their condition has now become available for treating it).

Furthermore, there are also quite a few medical indication patents which do not even remotely interfere with the clinician's activities, if not most of them. It does not seem to be good policy to abolish a system that seems to be largely in conformity with other principles and exceptions to patent law. Abolishing medical indication patents would then become a throwing away the baby with the bathwater scenario.

A means to avoid the baby and bathwater scenario could be to redefine what is a patentable medical indication patent. That would be a formidable task indeed. It would need to require some careful thought on what can and what cannot be patentable. If protection of health and the activities of the clinician were to take the forefront, it could be argued that the dividing line should be the extent to which the medical indication patent interferes with the activities of the clinician. If it does not, then it would be patentable; if it does, it would not be patentable. But that is also a very difficult line to draw. For instance, does the prescription of a patented dosage regime affect the clinician? At first glance the answer is negative. The patent for a dosage regime aims to protect the medicament for the use in that specific dosage, and not the prescribing behaviour of the clinician. That is only partly true, however. As we have seen in our contribution in the previous issue of this Journal, the mere fact of prescribing the patented dosage could trigger an infringement liability for the clinician. In other words, many medical indication patents could potentially trigger a liability risk for the clinician.

However, one should also not overrate the protection offered by the exclusion from patentability of medical treatment methods. The aim of that provision is not and has never been that a clinician should *never* be liable for patent infringement. That is also why "reconfiguring" medical indication claims or abolishing them altogether as they may present infringement risks for clinicians is as such not a sound policy decision.

That would leave the legislature with the evaluation of the opportunity cost of abolishing them anyway. Apart from the aforementioned legalistic objections, what would be the benefits and drawbacks of abolishing medical indication patents? That brings us back to the historical overview. The reason for having medical indication patents is often claimed to be to stimulate investment and innovation in the search for new treatments. In the absence of patent protection, that innovation would be lacking. This argument is very difficult to verify, and it brings us back to the fundamental rationale of the patent system in the first place. It would lead us too far to go into the details of the various economic and other rationales of the patent system.¹²³ Suffice to say here that in a world of personalised medicine, where it is effectively the case that treatments quite often reside in further medical indications of various formats (a new medical condition which can be treated with an existing drug, a new group of patients that has been identified which would benefit from treatment with an existing drug, the development of a specific dosage or administration regime for specific patients who would otherwise not benefit from the treatment, etc.), it is not an easy decision for a legislature to stand firm and say that there will be no patent protection for those treatments, creating the risk that research into these further treatments will come to a standstill, which could have not unimportant consequences in an era of personalised medicine.

And that brings me back to the point that I think the most important thing that needs to be done is to introduce a therapeutic freedom exception into the patent system. That would for a legislature at least "buy" the comfort that clinicians' activities are not jeopardised, even in the existence of patents.

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Footnotes

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¹ S.J.R. Bostyn, "Personalised Medicine, Medical Indication Patents and Patent Infringement: Emergency Treatment Required" [2016] I.P.Q. 151.

- 2 For a detailed analysis of this exclusion, see *E. Ventose, Medical Patent Law: The Challenges of Medical Treatment* (Cheltenham: Edward Elgar Publishing, 2011); P. Meier-Beck, "Patentschutz für die zweite medizinische Indikation und ärztliche Therapiefreiheit" [2009] G.R.U.R. 300; D. Thums, "Patent Protection for Medical Treatment—A Distinction between Patent and Medical Law" (1996) 27 I.I.C. 423; H. Schacht, *Therapiefreiheit und Patentschutz für die weitere medizinische Indikation* (Baden-Baden: Nomos Verlagsgesellschaft, 2014); Eva-Maria Müller, *Die Patentfähigkeit von Arzneimitteln: Der gewerbliche Rechtsschutz für pharmazeutische, medizinische und biotechnologische Erfindungen* (Berlin, Heidelberg: Springer-Verlag, 2003); R. Moufang, "Methods of Medical Treatment under Patent Law" (1993) 24 I.I.C. 18; D. Thomas, "Patentability Problems in Medical Technology" (2003) 34 I.I.C. 847; P. Lancon, "Patentability in the Field of Therapy and Diagnosis" (1991) 22 I.I.C. 893; K.E. Panchen, "Patentability in the Field of Therapy and Diagnosis" (1991) 22 I.I.C. 879; A. Feros, "Patentability of Methods of Medical Treatment" [2001] E.I.P.R. 79; A. Sims, "The Case against Patenting Methods of Medical Treatment" [2007] E.I.P.R. 43; J. Pila, "Methods of Medical Treatment within Australia and United Kingdom Patents Law" (2001) 24(2) University of New South Wales Law Journal 420.
- 3 *E. Ventose, Medical Patent Law* (2011), p.42.
- 4 In that sense also, see G2/08, [ABBOTT RESPIRATORY/Dosage regime](#), reasons 5.3.
- 5 Bristol Myers Squibb Co v F H Faulding & Co Ltd [2000] FCA 316 at [133]–[135].
- 6 *Travaux préparatoires* EPC 2000, art.53(c), CA/100/00 e.
- 7 Minutes of the Proceedings of the 12th meeting of the Patents Working Party held at Brussels from 26 February to 6 March 1964, 15 April 1964, 2632/IV/64-E, p.22.
- 8 See, e.g., Amendments to the Preliminary Draft Convention relating to a European Patent Law (Brussels, 22 January 1965), 2335/IV/65-E, art.9(2)(e); Preliminary Draft Convention for a European System for the Grant of Patents (Brussels, 25 July 1969), BR/6/69, p.17.
- 9 Badewasser, Beschwerdeabteilung II des Kaiserlichen Patentamtes, Bl.f.PMZ 1905, 4.
- 10 See, e.g., the decision of the German Federal Patent Court of May 11 1965, 7 BPatGE 83 (85)—Silikoseverhütung.
- 11 Bock, "Kann die Behandlung des lebenden menschlichen Körpers Gegenstand einer Erfindung im Sinne des Patentgesetzes sein?" [1927] G.R.U.R. 622; Dersin, "Über die Patentfähigkeit von Verfahren zur Behandlung des lebenden menschlichen Körpers (Dauerwell- und Haarfärbeverfahren)" [1951] G.R.U.R. 2; Herse, "Die Patentierbarkeit von Heilverfahren" [1905] G.R.U.R. 325; Marwitz, "Der Mensch im Patentrecht" [1930] G.R.U.R. 1078; Quade, "Kann der Mensch Gegenstand biologischer Patente sein?" [1913] G.R.U.R. 28.
- 12 BGH 26.09.1967 Ia ZB 1/65—Glatzenoperation [1968] G.R.U.R. 142.
- 13 BGH, 26 September 1967 Ia ZB 1/6—Glatzenoperation [1968] G.R.U.R. 142 at 146.
- 14 Federal Supreme Court (Bundesgerichtshof) 20 January 1977 Case: X ZB 13/75 — BPatG Benzene sulfonyl urea [1978] I.I.C. 42 at 44.
- 15 For a detailed analysis of the historical background of the exclusion in Australia and the UK, see Pila, "Methods of Medical Treatment within Australia and United Kingdom Patents Law" (2001) 24(2) University of New South Wales Law Journal 420.
- 16 [Statute of Monopolies 1623 \(21 Jac. 1 c. 3\) s.6](#): "Provided alsoe That any Declaracion before mencioned shall not extend to any tres Patents and Graunt of Privilege for the tearme of fowerteene yeares or under, hereafter to be made of the sole working or makeinge of any manner of new Manufactures within this Realme, to the true and first Inventor and Inventors of such Manufactures, which others at the tyme of makeinge such tres Patents and Graunts shall not use, soe as alsoe they be not contrary to the Lawe nor mischievous to the State, by raisinge prices of Commodities at home, or hurt of Trade, or generallie inconvenient; the said fourteene yeares to be [X]accomplished] from the date of the first tres Patents or Grant of such privilegede hereafter to be made, but that the same shall be of such force as they should be if this Act had never byn made, and of none other."
- 17 Decision of the Solicitor-General of 20 April 1914, [In the Matter of C and W's Application \(1914\) 31 R.P.C. 235](#).
- 18 See, e.g., the Australian case National Research Development Corp's Application [1961] R.P.C. 134 at 142: "The truth is that any attempt to state the ambit of [section 6 of the Statute of Monopolies](#) by precisely defining 'manufacture' is bound to fail. The purpose of [section 6](#), it must be remembered, was to allow the use of the prerogative to encourage national development in a field which already in 1623, was seen to be excitingly unpredictable. To attempt to place upon the idea the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the

notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept."

- 19 Decision of the Patents Appeal Tribunal of 9 July 1971, [Schering AG's Application \[1971\] R.P.C. 337](#) at 341.
- 20 [Schering AG's Application \[1971\] R.P.C. 337](#) at 343
- 21 [Schering AG's Application \[1971\] R.P.C. 337](#) at 343.
- 22 NRDC's Application [1961] R.P.C. 134.
- 23 [Schering AG's Application \[1971\] R.P.C. 337](#) at 342.
- 24 Decision of the Patents Appeal Tribunal of 11 July 11, 1974 [Eli Lilly & Co's Application \[1975\] R.P.C 438](#) at 445.
- 25 [Upjohn Co \(Robert's\) Application \[1977\] R.P.C. 94 CA \(Civ Div\)](#).
- 26 Then in s.4 of the [UK Patents Act 1977](#), amended by the [UK Patents Act 2004](#); now in s.4A.
- 27 Patentänderungsgesetz of 4 September 1967; BGH—Imidazoline [1972] G.R.U.R. 541.
- 28 A notable example is France, where there was since 1960 a so-called "brevet spécial de médicament". That special regime was abolished when the French Patent Act of 1968 provided for patent protection for pharmaceuticals. See Gerald Klöpsch, "Zur Schutzfähigkeit von Arzneimitteln nach dem Münchner Patentübereinkommen" [1982] G.R.U.R. Int. 102, 103.
- 29 For more details, see Bostyn, "Personalised Medicine, Medical Indication Patents and Patent Infringement" [2016] I.P.Q. 151, 155–158.
- 30 G5/83, [EISAI/Second medical indication \[1985\] OJ EPO 60](#).
- 31 Convention on the Unification of Certain Points of Substantive Law on Patents for Invention (Strasbourg, 27 November 1963).
- 32 Patent Cooperation Treaty, Done at Washington on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984, and on 3 October 2001, <http://www.wipo.int/pct/en/texts/articles/atoc.htm> [Accessed 17 June 2016].
- 33 Minutes of the Proceedings of the 12th meeting of the Patents Working Party held at Brussels from 26 February to 6 March 1964, 15 April 1964, 2632/IV/64-E, p.22.
- 34 Minutes of the Proceedings of the 14th meeting of the Patents Working Party held at Munich from 1 to 12 June 1964, 1 August 1964, 6498/IV/64-E, pp.13–15.
- 35 This last objection is interesting and shows how the world has changed over the years. At that time, it was believed that the chemical industry would still be the one inventing chemical molecules, while the pharmaceutical industry would only develop medical applications. As we now know, this has no longer been the case for many years.
- 36 Minutes of the Proceedings of the 15th meeting of the Patents Working Party held at Munich from 19 to 26 October 1964, and December 1964, 11821/IV/64-E, p.3.
- 37 It is interesting to observe here that during their discussions of the issues of medical indication patents the drafters were also discussing compulsory licensing schemes, so as to guarantee access to medicaments in reasonable quantities and at reasonable cost, which might be at risk as a consequence of introducing patent protection for pharmaceuticals.
- 38 See 2335/IV/65-E.
- 39 First Preliminary Draft of a Convention Establishing a European System for the Grants of Patents, 21 December 1970, BR/70/70, p.10.
- 40 Minutes of the 9th Meeting of Working Party I held from 12 to 22 October 1971 in Luxemburg, 17 November 1971, BR/135/71, p.48.
- 41 Minutes of the 5th Meeting of the Inter-Governmental Conference for the Setting up of a European System for the grant of Patents, Part II, Hearing of the non-governmental international organisations on the Second Preliminary Draft of a Convention establishing a European System for the Grant of Patents, Luxemburg, 26 January to 1 February 1972, BR/169/72, para.7, pp.8–9.

It is interesting to note here the argument that allowing patents for further medical indications would be more cost-effective and would provide access to medicaments more quickly than following the route of inventing a new chemical entity. With the benefit of hindsight one could be inclined to think that this was a clever strategic move by the pharmaceutical industry to make it look attractive to legislatures to allow medical indication patents in the interests of public health, while at the same time neatly hiding the fact that medical indication patents would in fact allow the pharmaceutical industry to make a relatively easy return on a relatively limited investment. One would get the impression that the pharmaceutical industry tried to externalise the risks of investing in new

- molecules to the legislature, almost making the latter responsible for the lack of new medicines if the search for new molecules were unsuccessful or at least slow.
- 42 So discussed in Federal Supreme Court (Bundesgerichtshof), 20 September 1983 Case No.X ZB 4/83 —Hydropyridine [1984] I.I.C. 215 at 221–222.
- 43 BR/199/72, p.56.
- 44 Minutes of the Third Meeting of the Co-ordinating Committee, Luxembourg, 23, 24 and 27 June 1972, 26 September 1972, BR/218/72, p.4–5.
- 45 Minutes of the Sixth Meeting of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents, Luxembourg, 19 to 30 June 1972, 26 September 1972, BR/219/72, points 30–32.
- 46 Draft Convention Establishing a European System for the Grant of Patents, 8 December 1972, M/1.
- 47 *Conference Document, Proposals for amendments to the drafts texts, Netherlands delegation, 10 September 1973, M/52/IIII/III.*
- 48 See, e.g., V. Vossius, "Der Patentschutz von Verwendungserfindungen auf dem Gebiet der Pharmazie nach geltendem und zukünftigem Deutschen und Europäischen Patentrecht unter besonderer Berücksichtigung der zweiten Indikation" [1978] G.R.U.R. 7; V. Vossius and P. Rauh, "Patentierbarkeit der zweiten Indikation—(Ergänzung zu GRUR 1978 7-15)" [1980] G.R.U.R. 776; G. Bühling, "Die Bedeutung von Arzneimittelansprüchen für den Patentschutz von Verwendungserfindungen nach dem neuen deutschen und europäischen Patentgesetz" [1978] G.R.U.R. 15; G. Klöpsch, "Zur Schutzfähigkeit und zum Schutzzumfang der sogenannten zweiten Indikation im deutschen und europäischen Patentrecht" [1979] G.R.U.R. 283; H.-D. Nahme, "Besonderheiten für Pharmazie-Patente nach den Europäischen Übereinkommen" [1978] G.R.U.R. Int. 188.
- 49 See Werner Stieger, "Artikel 54 Abs. 5 des Münchener Patentübereinkommens: Eine pharmazeutische Sondernorm" [1980] G.R.U.R. Int. 203, 208.
- 50 Bernd Hansen, "Zum Patentschutz der 2. Indikation" [1977] G.R.U.R. 15; Stieger, "Artikel 54 Abs. 5 des Münchener Patentübereinkommens" [1980] G.R.U.R. Int. 203, 211; undecided, see Wilhelm Trustedt, "Zur Patentierbarkeit der weiteren medizinischen Indikation" [1983] G.R.U.R. 478.
- 51 See *Schacht, Therapiefreiheit und Patentschutz für die weitere medizinische Indikation (2014)*, p.264, and further references there.
- 52 *R. Urich, Stoffschutz (Tübingen: Mohr Siebeck, 2010)*, pp.402–403.
- 53 BGH, 20 January 197—Benzolsulfonylharnstoff BGHZ 68, 156, 161; [1977] G.R.U.R. 652.
- 54 e.g., Stieger, "Artikel 54 Abs. 5 des Münchener Patentübereinkommens" [1980] G.R.U.R. Int. 203, 208.
- 55 e.g., Volker Vossius and Peter A. Rauh, "Patentierbarkeit der zweiten Indikation" [1980] G.R.U.R. 776, 777.
- 56 *Hans-Rainer Jaenichen, Jürgen Meier and Niels Hölder, "Medical Use Claims: EPC 2000 and its Impact on Prosecution and Enforcement" in W. Prinz zu Waldeck und Pyrmont, M.J. Adelman, R. Brauneis, J. Drexler and R. Nack (eds), Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus (Berlin, Heidelberg: Springer-Verlag, 2009)*, p.255 at p.266.
- 57 BGHZ 101, 159—Antivirumittel [1987] G.R.U.R. 794 at 797: "Die vorstehenden Ausführungen gelten im Ergebnis unabhängig davon, ob man den Klagepatentanspruch als 'zweckgebundenen Stoffanspruch' oder als einen Verwendungsanspruch im Sinne der neueren Rechtsprechung des erkennenden Senats ('Benzolsulfonylharnstoff' und 'Sitosterylglykoside', a.a.O.) auffaßt."
- The literature seems to agree with this stand: see, e.g., *Rudolf Kraßer, Patentrecht. Ein Lehr- und Handbuch zum deutschen Patent- und Gebrauchsmusterrecht Europäischen und Internationalen Patentrecht, 6. Auflage (München: Verlag C.H. Beck, 2009)*, p.780.
- 58 See, e.g., Peter Krasa, "Zur Schutzfähigkeit der 2. Indikation" [1977] G.R.U.R. 476, 477.
- 59 See, e.g., Gerald Klöpsch, "Zur Schutzfähigkeit von Arzneimitteln nach dem Münchner Patentübereinkommen" [1982] G.R.U.R. Int. 102.
- 60 G5/83, [EISAI/Second medical indication](#) [1985] OJ EPO 60.
- 61 G5/83, [EISAI/Second medical indication](#), reasons 23.
- 62 Arrêt de la Cour de cassation, chambre commerciale, du 26 octobre 1993, Alfuzosine [1995] OJ EPO 252.
- 63 See, e.g., UK High Court of Justice, *WYETH and SCHERING/Second medical use* [1986] OJ EPO 175; NL Octrooiraad, *Afdeling van Beroep (Appeal Division of the Patent Office)*, *NL/Second medical use* [1988] OJ EPO 405; SE Patentbesvärätten (Court of Patent Appeals), *SE/*

- Hydropyridine/SE [1988] OJ EPO 198; FR Cour de cassation, Alfuzosine [1995] OJ EPO 252. In the specific case in question, the Octrooiraad did not grant the patent. In a more recent decision of the UK High Court handed down in 1998 ([Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc \[1999\] R.P.C. 253 Ch D](#)), substantial doubts were expressed as to the novelty of "Swiss claims". See, for this, *travaux préparatoires* EPC 2000, art.54(5), CA/PL 4/00, para.6.
- 64 Federal Supreme Court (Bundesgerichtshof) 20 September 1983 Case No.X ZB 4/83—Hydropyridine [1984] I.I.C. 215.
- 65 *R. Singer, Das Neue Europäische Patentsystem (Baden-Baden: Nomos Verlagsgesellschaft mbH & Co KG, 1979), para.2.3.4.1, p.40*; R. Singer, "Das materielle europäische Patentrecht" [1974] G.R.U.R. Int. 61; *F. Panel, La protection des inventions en Droit européen des brevets (Paris: Litec, 1977), p.64, paras 110 and 111*; *Paul Mathély, Le droit européen des brevets d'invention (Paris: Librairie du Journal des Notaires et des Avocats, 1978), p.166*; *M. van Empel, The Granting of European Patents (Dordrecht, Boston: Kluwer Academic Publishers, 1975), p.66, para.122*.
- 66 Federal Supreme Court (Bundesgerichtshof) 20 September 1983 Case No.X ZB 4/83—Hydropyridine [1984] I.I.C. 215 at 223.
- 67 Hydropyridine [1984] I.I.C. 215 at 223–224.
- 68 [John Wyeth and Brothers Ltd's Application and Schering AG's Application \[1985\] R.P.C. 545](#).
- 69 [Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc \[2001\] R.P.C. 1 CA \(Civ Div\)](#).
- 70 [Actavis UK Ltd v Merck & Co Inc \[2008\] EWCA Civ 444](#); [2008] R.P.C. 26 at [59].
- 71 G2/08, [ABBOTT RESPIRATORY/Dosage regime \[2010\] OJ EPO 456](#), reasons 7.1.3.
- 72 See, for this, *travaux préparatoires* EPC 2000, art.54(5), CA/PL 4/00.
- 73 [Bristol Myers Squibb v Faulding \[2000\] FCA 316](#) at [15].
- 74 For an extensive overview of arguments, see *Ventose, Medical Patent Law (2011), pp.43–70*.
- 75 *S. Bostyn and N. Petit, "Patent=Monopoly — A Legal Fiction" (December 31, 2013), SSRN, <http://ssrn.com/abstract=2373471> [Accessed 17 June 2016]*.
- 76 For a detailed discussion, see *S.J.R. Bostyn, "Personalized Medicine, Intellectual Property Rights and Human Rights" in P. Torremans (ed.), Intellectual Property Law and Human Rights, 3rd edn (Alphen aan de Rijn: Kluwer Law International, 2015), pp.758–782*; *Laurence R. Helfer and Graeme W. Austin, Human Rights and Intellectual Property: Mapping the Global Interface (New York: Cambridge University Press, 2011), pp.90–170*; *Laurence R. Helfer, "Mapping the interface between human rights and intellectual property" in C. Geiger (ed.), Research Handbook on Human Rights and Intellectual Property', Research Handbooks in Intellectual Property series (Cheltenham: Edward Elgar, 2015), pp.6–15*.
- 77 The Australian Federal Court said in that connection that "there now appears to be general consensus that medical and surgical products are appropriate subject matter for patents ... This is so notwithstanding the fact that many patients (perhaps millions around the world) are denied access to new pharmaceuticals, because of the price charged by the monopolist or its licensee." See [Bristol Myers Squibb v Faulding & Co \[2000\] FCA 316](#) at [132].
- 78 [Bristol-Myers Squibb v Baker Norton \[1999\] R.P.C. 253](#) at [51].
- 79 [Bristol-Myers Squibb v Baker Norton \[2001\] R.P.C. 1](#) at [62].
- 80 The UK court in the [BMS](#) case saw some second medical indication patents as nothing more than hidden medical treatment methods: see [Bristol-Myers Squibb v Baker Norton \[2001\] R.P.C. 1](#). The Court of Appeal in a later case felt itself not bound by the precedent for reason that the ratio of [BMS](#) was not clear: see [Actavis v Merck \[2008\] EWCA Civ 444](#); [2008] R.P.C. 26 at [84].
- 81 e.g. the case of gefitinib: "In December 2004, gefitinib failed to show significant benefits in an overall population of patients with lung cancer in a Phase III clinical study. It could not therefore enter the European market and appeared to be a failure. But, gefitinib made a surprise comeback. The reason is that it was discovered a sub-population of about 10–15% of lung cancer patients having tumours with a mutation in the epidermal growth factor receptor for tyrosine kinase (EGFR-TK) responded particularly well to the drug. This is because gefitinib inhibits the EGFR-TK activity that promotes the growth of certain lung cancer cells. Subsequently, in June 2009, gefitinib was granted marketing authorisation for the treatment of adults with locally advanced or metastatic non-small cell lung cancer who present positive for mutations of EGFR-TK. Shortly afterwards, the drug was recommended by the National Institute for Health and Care Excellence (NICE) in the UK as a first line treatment option". Taken from: *Taylor Wessing, "Personalised medicine — patenting new drugs from old?" (October 2013), <http://www.taylorwessing.com/synapse/october13.html> [Accessed 17 June 2016]*.

A biomarker can be defined as a characteristic that is objectively measured and evaluated as an indicator of normal biological processes, pathogenic processes, or pharmacological responses to a therapeutic intervention. See H. Salter and R. Holland, "Biomarkers: refining diagnosis and expediting drug development — reality, aspiration and the role of open innovation" (2014) 276 *Journal of Internal Medicine* 215, 215.

- 82 T19/86, [1989] OJ EPO 24; T893/90 of 22 July 1993; T233/96 of 4 May 2000.
 83 T51/93 of 8 June 1994; T138/95 of 12 October 1999.
 84 T290/86, [1992] OJ EPO 414; T254/93, [1998] OJ EPO 285; T1020/03, [2007] OJ EPO 204.
 85 G2/08, [ABBOTT RESPIRATORY/Dosage regime \[2010\] OJ EPO 456](#).
 86 e.g. T19/86, [DUPHAR/Pigs II \[1989\] OJ EPO 24](#), at 8 of the reasons; T893/90, *QUEEN'S UNIVERSITY KINGSTON /Controlling bleeding*, decision of 22 July 1993, at 4.2 of the reasons.
 87 T233/96, *MEDICO RESEARCH/Adrenaline*, decision of 4 May 2000.
 88 T233/96, *MEDICO RESEARCH/Adrenaline*, Headnote I.
 89 Surprisingly, the case law handbook edited by the Legal Research Service of the Boards of Appeal still refers to the T233/96 as valid case law; see *Legal Research Service of the Boards of Appeal, Case Law of the Boards of Appeal, 7th edn (European Patent Office, 2013)*, pp.147–148.
 90 T1399/04, *SCHERING/Combination therapy HCV*, decision of 25 October 2006.
 91 T1399/04 *SCHERING/Combination therapy HCV* at 35 of the reasons.
 92 T1399/04 *SCHERING/Combination therapy HCV* at 35 of the reasons.
 93 T734/12, *GENENTECH INC/Arthritis patients with an inadequate response to a TNF-alpha inhibitor*, decision of 17 May 2013.
 94 T734/12, at 24 of the reasons.
 95 G2/88, *MOBIL OIL III/ Friction reducing additive* [1990] OJ EPO 93, reasons at 10.1.
 96 G2/88, reasons at 10.3.
 97 [Merrell Dow Pharmaceuticals Inc v H.N. Norton & Co Ltd \[1996\] R.P.C. 76 HL](#) at 84.
 98 [Actavis v Merck \[2008\] EWCA Civ 444; \[2008\] R.P.C. 26](#) at [21].
 99 [Bristol-Myers Squibb v Baker Norton \[2001\] R.P.C. 1](#) at [63].
 100 [Merck & Co Inc's Patents \[2003\] EWHC 5 \(Pat\); \[2003\] F.S.R. 29](#).
 101 It concerned a request to amend claim 1 of the EP 0 998 292 patent, which amendment read: "Use of alendronic acid, or a pharmaceutically acceptable salt thereof, for the manufacture of a medicament for inhibiting bone resorption for treating osteoporosis in a human in need thereof wherein such medicament is adapted for administration in a unit dosage form which comprises about 70mg of alendronic acid or a pharmaceutically acceptable salt thereof, on an alendronic acid active weight basis, according to a continuous schedule having a dosing interval of once weekly."
 102 [Merck & Co Inc's Patents \[2003\] EWHC 5 \(Pat\), \[2003\] F.S.R. 29](#) at [71].
 103 [Merck & Co Inc's Patents \[2003\] EWHC 5 \(Pat\); \[2003\] F.S.R. 29](#) at [80].
 104 [Actavis v Merck \[2008\] EWCA Civ 444; \[2008\] R.P.C. 26](#) at [59].
 105 Decision Federal Supreme Court (Bundesgerichtshof) of 19 December 2006—Case No.X ZR 236/01—*Carvedilol II* [2007] I.I.C. 479 at 487.
 106 Decision Federal Supreme Court (Bundesgerichtshof) of 19 December 2006 — Case No.X ZR 236/0—*Carvedilol II* [2007] I.I.C. 479 at 482–483.
 107 LG Hamburg, Urteil of 2 April 2015 — 327 O 143/15, BeckRS 2015, 08691.
 108 G2/08, reasons at 5.7.
 109 G2/08, reasons at 5.8.
 110 G2/08, reasons 5.9.1.1 to 5.9.1.2.
 111 G2/08, reasons at 5.10.3. Ventose is of the view, in my opinion erroneously, that the text of art.54(5) EPC 2000 suggests that only a new illness to be treated can be covered. See *Ventose, Medical Patent Law (2011)*, p.273. I cannot possibly see how such a conclusion could be drawn from the text of the provision or from the *travaux préparatoires*. I am supported in my view at least by Jacob LJ in [Actavis v Merck \[2008\] EWCA Civ 444; \[2008\] R.P.C. 26](#).
 112 T19/86, [1989] OJ EPO 24; T893/90 of 22 July 1993; T233/96 of 4 May 2000, all relating to a novel group of subjects treated. T51/93 of 8 June 1994; T138/95 of 12 October 1999, both relating to a new route or mode of administration. T290/86, [1992] OJ EPO 414; T254/93, [1998] OJ EPO 285, relating to a different technical effect and leading to a truly new application as set out in T1020/03, [2007] OJ EPO 204.
 113 G2/08, reasons at 5.10.8.
 114 [Schering AG's Application \[1971\] R.P.C. 337](#) at 343.
 115 [Bristol-Myers Squibb v Baker Norton \[1999\] R.P.C. 253](#) at [51].

- 116 On therapeutic freedom exception, see Bostyn, "Personalised Medicine, Medical Indication Patents and Patent Infringement" [2016] I.P.Q. 151, 189.
- 117 See *Ventose, Medical Patent Law (2011)*, pp.50–52. Compulsory licensing could be a remedy in case of refusal to provide access, but that is a very burdensome procedure which is fraught with problems and uncertainties. I hence do not think this can reasonably be seen as an efficient solution.
- 118 As we have seen, in Europe, the non-patentability of medical treatment methods has been defended for many years on the basis of socio-ethical concerns. It would be somewhat illogical if those same legislatures would suddenly decide that those concerns are no longer present.
- 119 For more details on the right to health in the context of patent law, see Bostyn, "Patenting personalised medicine and human rights" in *P. Torremans (ed.), Intellectual Property and Human Rights (2015)*, pp.771–782, and the references therein.
- 120 Bristol Myers Squibb v Faulding [2000] FCA 316 at [133]–[135].
- 121 About which details can be found in Bostyn, "Personalised Medicine, Medical Indication Patents and Patent Infringement" [2016] I.P.Q. 151, [2016] I.P.Q. 151.
- 122 *European Commission, Pharmaceutical Sector Inquiry, Final Report (8 July 2009)*, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf [Accessed 17 June 2016].
- 123 For a detailed overview of the various rationales and theories of patent protection with multiple references, see *S.J.R. Bostyn, "Enabling Biotechnological Inventions in Europe and the United States: A study of the patentability of proteins and DNA sequences with special emphasis on the disclosure requirement", Eposcript Series, No.4 (EPO, München, 2001)*, pp.23–64.

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