The Intricacies of Partly New Inventions: Should We Grant Patentability?

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This article addresses the issue of partly new inventions and the possibility of granting them patentability. The route of the analysis starts with the identification of the sectors in which this issue frequently arises. It consequently continues with finding and locating all those common characteristics of the circumstances under which the ‘phenomenon’-in-question arises. The interesting conclusion of this analysis is that the phenomenon of partially new inventions being granted patentability occurs mainly within the pharmaceutical (and chemicals) sector. This realization leads to even more substantial concerns, especially from a competition law perspective. That is because pharmaceutical (and chemicals) companies apply for – and get granted- patentability of partly new inventions to a wide extent. One of the questions at this point is whether this is causing a restriction to competition by threatening the delicate balances of the specific market. This question is answered through references not only to the law itself, including leading case-law from both the EU and the UK, but also to policy concerns and market-related considerations. Finally, the aforementioned findings are used in order to address the question of whether patentability should be granted to partly new inventions, whilst following a further analysis and assessment of relevant competition -and other- policy issues.

Keywords: patents, European Union, EPC 1973, EPC 2000, pharmaceuticals, competition law.

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1. INTRODUCTION

Patentability is granted where the claimed invention fulfills the requirements of novelty, inventiveness and industrial application\(^2\). That means that the invention would have to be new\(^3\); that it is not obvious to the person skilled in the art\(^4\); and that it can have a use in industry\(^5\). What about the case, though, when a claimed invention is not entirely new? Can it be granted patentability? And if so, under which requirements? In the present essay we will look into the issue of patentability for partially new inventions. In Chapter II we will identify the problematic areas of partially new inventions; in chapter III we will present the issue of inventive step with regards to these inventions; and in chapter IV we will look into the policy rationale of granting patentability for partially new inventions by taking into consideration the particularities of the sectors from where these inventions are derived.

2. NOVELTY

When an invention is ‘new’ in its totality, then there is no problem; it can be declared new, thus fulfilling the novelty requirement and passing the first ‘test’ of patentability. Problems, however, arise in circumstances where some parts are new and some are not; thus novelty, we could say, is marginal\(^6\). In the present chapter, we will examine the instances where an invention is considered new in part. In that regard, we will look into the specific categories of inventions that have caused the most problems and subsequent critique: we will first examine the case of exceptions to the medical/pharmaceutical field, then the exception to non-medical uses and finally, we will examine the issue of selection patents.

2.1. An exception to an exception: The case of medicine and pharmaceuticals

Article 52(1) of the 1973 EPC stated in substance that patentability could be recognized in inventions which are novel, inventive and industrially applicable, so that new uses for known products can be protected as such by

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\(^3\) UK Patent Act 1977, s. 1 (1) (a).
\(^4\) UK Patent Act 1977 s. 3.
claims directed to that use. That was valid for all fields but one: the field of making products for use in surgery, therapy and diagnostic methods. However, an exception laid in 54(5) EPC 1973 (and the relevant s. 2(6) of the 1977 Act), namely that so far as the first use of medicaments is concerned, the required novelty for the medicament, which forms the subject-matter of the claim, is derived from the new pharmaceutical use. Than meant that if a known drug would be used for a new treatment, then novelty could be claimed. The limitation inherent therein was that the known substance should not have been known to have any medicinal use before. However, soon enough, practice showed that novelty could be claimed not only for the first medical use, but also for any –second- subsequent use. That was the conclusion of the Eisai/Second Medical Indication Case\(^7\) on the European Level and the John Wyeth\(^8\) case in the UK. Both cases concluded that art. 54 (5) of the EPC and s. 2 (6) of the Act also applied to second medical uses, rather than just first ones, under the requirement that claims for second medical use were introduced in the form of ‘Swiss-type claims’: ‘use of substance X for the manufacture of a medicament for the treatment of Y’. That was the case, because, if the form ‘use of substance X for the treatment of Y’ was used, then such claims would fall under the exception of ‘methods of treatment’\(^9\), whereas Swiss type claims were focused on the manufacture of the medicament by using the known substance in question, thus deriving their novelty from the new therapeutic use\(^10\) (purpose). After the first cases, others followed\(^11\). So it became clear that when an old drug was used for the treatment of a different disease, novelty could be granted.

What about the case though, when the known drug would treat the same disease but the alleged novel part was that of the method of administration or dosage? The opinions on the European and UK level differ; EPC 1973 in its application by the EBoA came to cover patentability of substances and compositions known in the prior art for use in the treatment by therapy of a particular disease, even if they were directed to the treatment of the same illness, provided this treatment was new and inventive; that was enshrined in rigorous case law\(^12\). Hence, new use could either mean that a disease could be now treated by the claimed substance/composition, or that it included different steps applicable (by their nature) to a therapeutic method which may not be

\(^{7}\) Eisai, G5/83 [1985] OJ EPO 64.

\(^{8}\) John Wyeth & Brother Ltd’s Application [1985] RPC 545.

\(^{9}\) Article 52 (4) of the EPC and s 4 (2) of the Act.


\(^{11}\) See (G-1/83) Bayer and (G-7/83) Pharmuka, Decision of the Enlarged Board of Appeal dated December 5, 1984 [1985] OJ EPO 60.

claimed as such. In the UK, there had been doubts, until they eventually permitted the aforementioned practice, thus following the decisions of Eisai and Genentech.

As is probably assumed, the use of Swiss-type claims brought much criticism, due to the problematic ‘functional relationship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process’.

After the 2000 revision of the EPC, and while EPC 1973 (decision Eisai G5/83) allowed claims directed to the use of a substance for the manufacture of the drug for a therapeutic indication ("Swiss-type claims"), art. 54 (5) now explicitly permits the use of purpose-related product claims, directed to the substance itself. Following that, the UK also implemented that development in art 4A (4) of the Act. So, now, purpose-related product protection can be officially granted for second medical uses. How should these be claimed now, though?

As noted in the Dosage regime/ABBOTT RESPIRATORY case, “It appears that the rights conferred on the patentee by the claim category under Art. 54(5) EPC are likely broader, and could, in particular, lead to possible restrictions on the freedom of medical practitioners to prescribe or administer generics.” That being said, the Board, concluded that, patent applications filed from 29 January 2011 and with no earlier priority date will not be granted European patents under Swiss-type use claims, where the subject

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18 The new Article 54(5) EPC eliminates any legal uncertainty on the patentability of further medical uses. It unambiguously permits purpose-related product protection for each further new medical use of a substance or composition already known as a medicine’, explanatory notes MR/l8/00, point 4.
22 Julian Cockbain, Sigrid Sterckx, ‘Is the Enlarged Board of Appeal of the European Patent Office authorised to extend the bounds of the patentable? The G5/83 Second Medical
matter of a claim was rendered novel only by a new therapeutic use of a medicament (for example, a new dosage). Even though that does not exclude the possibility of granting patents where, for example, a dosage regime is the only novel feature claimed, it subsequently creates a blurry veil of uncertainty on cases which were granted patentability where the only novel element was for example, dosage regimes, under Swiss-type claims.23

2.2. Non-Medical Use

The novelty of purpose applied in the medical field was applied in a non-medical field in the Mobil/Friction Reducing Additive case.24 The patent in question related to the use of a known compound for use as an additive for lubricant oils. An earlier patent had been granted for the same additive and the same use. What the patentees claimed here as novel, was the purpose, namely, the purpose of reducing friction between sliding surfaces in an engine. The formulation of the problem here was the following: old substance, old use, new purpose: could this be considered novel? The EBoA, in this highly contentious case, concluded to the affirmative.

This case was in essence, a matter of second non-medical use, following the Eisai Case,25 even though the Board made sure to distinguish between the differences it found in these two cases.26 In brief, the Court stated that this new use claimed by the patentees ought to have a technical effect accompanying the use, thus resulting in a technical feature that becomes part of the subject-matter of the use claim.27 In this way, novelty will be declared, as long as this technical effect had not been ‘made available to the public’ through its previous use, despite the fact that this technical effect might have taken place during the previous use.28 This last part reflected the shift of the English law regarding the lack of novelty in an invention which had previous secret use, in the sense that that secret use anticipated the later invention. Furthermore, in Robertet/Deodorant compositions it was submitted that the patentee has to

Indication/EISAI and G2/08 Dosage Regime/ABBOTT RESPIRATORY cases’, IIC 2011, 42(3), 257-271 at 258.
23 See for example Actavis UK v Merck [2008] EWCA Civ 444 (CA).
25 Eisai Case, supra note 6.
27 In the sense that, as Bently states, achieving the new purpose is seen as a ‘technical feature’ of the invention, Lionel Bently, supra, 483.
28 Supra at 10.3
29 See Bristol Myer’s Application [1975] RPC 127, which was under the Patent Act 1949.
30 T892/94 [1999] EPOR 516, 526, where novelty of purpose was not granted for the effect of the aromatic esters on the human skin, based on the argument that claimed effect was nothing more than a disclosure of already existing information.
submit a new purpose and that disclosure of already existing information would not grant novelty\textsuperscript{31}. This meant that novelty could be recognised with regards to ‘technical effects’ under the aforementioned requirements.

The Mobil case represents good law in the UK that not only relates to chemical compounds, but also to other non-medical areas that strive to discover new applications of already known compounds\textsuperscript{32}. However, one should underline the legitimate concerns that followed it. \textit{First}, as Aplin\textsuperscript{33} notes, following the opinion of Lord Hoffmann in Merrell Dow v Norton\textsuperscript{34}, allowing such novelty of purpose claims can have significant negative impact on deciding patent infringement, since there is no way of knowing whether using the known substance is done with the old or new purpose in mind, thus creating an uncertain ground for infringement. The \textit{second} problem derives from a competition law perspective: the Mobil case had the important negative effect of allowing re-monopolisation of the same substance that had been monopolised through the first patent\textsuperscript{35}.

2.3. Selection Patents

The third main area where an invention could be considered partially new is the area of selection patents, mainly referring to –but not exclusively confined to- chemicals\textsuperscript{36}. When a scientist is doing research, he/she makes different combinations of compounds, which result in broad classes of chemicals, the specific uses or advantages of which have not been discovered usually. In general, this extensive monopoly –which not only distorts the market but also acts as a disincentive for further research- is balanced with selection patents, under which, even though a generic disclosure of the class of chemicals had occurred already, the second patentee may be granted a patent for a selection of substances from the general class as disclosed by the first research\textsuperscript{37}.

The problem inherent to selection patents is visible already from the description: can one really declare something novel if it had already been disclosed? Moreover, had that disclosure established anticipation? A first answer was given by the IG Farbenindustrie case\textsuperscript{38}, which set three conditions

\textsuperscript{32} As noted by Bently in Lionel Bently, \textit{supra}, p 482.
\textsuperscript{34} [1996] RPC 76, 92.
\textsuperscript{35} Catherine Colston and Jonathan Galloway, \textit{supra}, 183-184.
\textsuperscript{36} Catherine Colston and Jonathan Galloway, \textit{supra}, 180.
\textsuperscript{37} The first case to consider selection patents in the UK was \textit{IG Farbenindustrie} [1930] 47 RPC 289, 322-3.
\textsuperscript{38} \textit{IG Farbenindustrie} [1930] 47 RPC 289.
for a selection patent to be valid\(^39\): first, that the selection was based on substantial advantage resulting from the use of selected parts, second that all these selected parts demonstrated this advantage and third, that in the case certain quality was the basis of the selection, then this quality should be also unique\(^40\) to the selected members of the group\(^41\). Selection patents thus, are founded on ‘new uses’\(^42\), although not limited to them\(^43\). Even though the patent in this case was not held to be valid after all, numerous cases that followed it\(^44\), relied on it and explored further the notion of selection patents, usually resulting in the validation of selection patents.

The situation has now changed after Dr. Reddy’s Laboratories Ltd v Eli and Co Ltd\(^45\), mostly with regard to the aforementioned conditions set as rules to decide on patentability. Jacob LJ mentioned\(^46\) that IG Farbenindustrie should not be followed, since, first, it was under the old law of 1949 which did not identify between novelty and inventive step (in fact, the conditions themselves in this case portray this confusion), second, the EPO had never used these or any equivalent conditions or rules with regards to selection patents; and finally, third, it made things difficult for the patentee, since he/she would have to engage in multiple and (maybe unrealistically) extensive experimentation in order to prove that the selected class had a substantial advantage\(^47\). Instead, the Court decided to follow the EPO Board’s approach, which is more novelty- and non-obviousness-oriented. In this way, selection patents will not be treated as an exception to the novelty rules. It should be pointed out at this point that EPO’s case law treats selection patents under the general novelty requirements\(^48\). This means\(^49\) that the previous disclosure of

\(^{39}\) Note however that Torremans, Holyoak and Torremans, supra, 70; see also Lionel Bently, supra 2009, 485, who places these requirements under novelty, whereas Winfried Tilmann sets them under inventive step; see Winfried Tilmann, ‘Validity of selective product claims’, Venice Conferences III and V, Lundbeck and Olanzapin, IIC 2010, 41(2), 149-169, at 160.

\(^{40}\) On this point see also Shell Refining Marketing & Marketing Co Ltd [1960] RPC 35 at 55.

\(^{41}\) See further Lionel Bently, supra, 485, Aplin, supra, 679-680, Colston, supra, 181.

\(^{42}\) Colston, supra, 181.

\(^{43}\) Lionel Bently, supra, 486 where he states that they can also apply to the discovery of new substances, new uses for old substances or even new purposes for old substances processed in old ways.

\(^{44}\) See especially the last case under the previous law: El Du Pont de Nemours & Co’s (Witsiepe’s) Application [1982] FSR 303; Boehringer Mannheim v Genzyme [1993] FSR 716; Beecham Group Ltd v Bristol Laboratories International SA [1978] RPC 521.


\(^{46}\) Ibid. at 35-37.

\(^{47}\) Ibid. at 39.


the class will have to be enabling\textsuperscript{50}, in the sense that the disclosure allows the skilled person to work on the invention\textsuperscript{51}.

3. INVENTIVE STEP

The next condition that needs to be fulfilled so that an invention is patentable, is s. 3 of the Act\textsuperscript{52}. According to this condition, unless the invention is obvious to a person skilled in the art, ‘having regard to any matter which forms part of the state of the art’, it will involve an inventive step; hence it will fulfil the condition spelled out in s. 3 of the Act. It ensures a qualitative assessment of the patent which results in patenting meritorious\textsuperscript{53} inventions instead of obvious ones, which would imply only repeating or slightly modifying prior art\textsuperscript{54}.

3.1. Assessing the problems of inventiveness

The case law on the patentability requirement of inventive step has been extensive. Besides the guidance it has provided us with, it has revealed many problematic areas in situations when only ‘partial novelty’ exists, thus rendering the clarity of the inventive step requirement harder. These problems will be discussed in this sub-chapter.

3.1.1. Partial Novelty in the Medical/ Pharmaceutical/ Chemistry Sector

It is now widely known that the Windsurfing case\textsuperscript{55} introduced an inventiveness test comprising four gradual questions\textsuperscript{56} in order to decide

\textsuperscript{50} See Synthon BV v Smithkline Beecham plc [2005] All ER (D), 235, [2006] RPC 10 (HL), where the test applied was not enabling disclosure, but two different elements: disclosure and enablement.

\textsuperscript{51} See Bently, supra, 486-487.

\textsuperscript{52} And subsequent article 56 of the EPC.

\textsuperscript{53} Tanya Aplin, Jennifer Davis, supra, 685.


\textsuperscript{55} Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] RPC 59.

\textsuperscript{56} The questions are: (1) identify the inventive concept embodied in the patent in suit; (2) assume the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art in question; (3) identify what, if any, differences exist between the matter cited as being [state of the art] and the alleged invention; (4) ask whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they require a degree of invention Windsurfing International Inc v Tabur Marine (Great Britain) Ltd [1985] R.P.C. 59 at 73-74.
whether something is obvious or not. That test was later on modified when the Court of Appeal was considering the Pozzoli case\(^{57}\) (Pozzoli test). So, now the first question of the test regards the ‘normally skilled but unimaginative addressee in the art’ and the common general knowledge in the art-in question that can be attributed to him/her. The test itself had raised many questions relating to its effect, until it was held in the Conor case\(^{58}\) that the test was to be seen as a guideline and not as a route to a definitive answer.

Further—and more intense—questions\(^{59}\) had been raised regarding the addressee of the test. The Pfizer case\(^{60}\) showed that this person is just a creation made up to serve the purposes of the test and that it did not correspond to a real person. It was also held in the same case that this creation, this person, has relevant knowledge of the particular field discussed pertaining to the patent. Is that person the same in any case?

Genentech\(^{61}\) concluded that it isn’t. In particular, it stated that due to the highly intellectual area (biotech), the hypothetical addressee should raise the bar high\(^{62}\); because of the nature of the field, where invention is a primary goal that characterises to a wide extent the industry, the ‘person skilled in the art’ should also have inventive capacity. That can have significant repercussions on relevant fields, such as the ones where partially-new ‘inventions’—in the broad sense—exist, namely medicine, pharmaceuticals and chemicals. In these areas, most of the researchers have obtained high education, including usually a PhD or equivalent\(^{63}\). The result of that would be that in all the relevant fields, such as the ones we are discussing, solutions (or developments) that are considered as an inventive step, are classified as obvious\(^{64}\), going against the letter of s. 3 of the Act.

Another view expressed in the same case that could prove problematic for the particular fields under review now, is the view expressed by Mustill LJ\(^{65}\) that the time and money spent on the particular research do not suffice and that the law as it is, needs something additional. Even though it appears to be a fairly legitimate aspect, it should be noted that especially in the fields-in-question, time and money spent on any research can reach to significant amounts, not to mention that, as Purchas LJ\(^{66}\) suggested, to the contrary,

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\(^{57}\) Pozzoli SPA v BDMD SA [2007] FSR 37 (CA).
\(^{58}\) Conor Medsystems Inc v Angiotech Inc [2007] ECWA Civ 5.
\(^{59}\) See further Holyoak and Torremans, supra, 76-79.
\(^{62}\) ibid., at 214
\(^{63}\) See Torremans, supra, 81-82.
\(^{64}\) Ibid., 89.
\(^{65}\) Genentech, supra, 280.
\(^{66}\) Ibid., 221.
significant time and money expenditures may actually provide a good indication of the non-obviousness of the subject-matter.

Finally, another problem created with a focus on the partial novelty discussed in the previous chapter, is exactly this: that not everything is new. So how will be decided whether the step made forward is an inventive one? If one follows the same logic adopted in Genentech\textsuperscript{67}, then in most of the cases that we described above, most of the materials, are lying on the road and ‘are available for the research worker to pick them up’. Furthermore, since inventiveness needs to be assessed at every research stage, then that would imply that the focus should concentrate on ‘the process and the materials employed, rather on their use and consequences’\textsuperscript{68}, in contrast to what Dillon LJ submitted in Genentech\textsuperscript{69}. If that’s the case, then proving that a ‘clear inventive step’ occurred might become significantly burdensome for firms of the sectors-in-questions whose alleged step forward might be ‘merely’ one novel aspect (use or purpose)\textsuperscript{70}.

3.1.2. Selection Patents

When it comes to selection patents, the first problem identified is one of clarity between the novelty and inventive step requirement. As noted before\textsuperscript{71}, opinions differ, which could also have to do with the inconsistencies sometimes noted on the European level\textsuperscript{72}. Besides that, another problem that might arise in this instance is relatively obvious: since the broader class the selected members belonged to was known, how will obviousness be assessed? The researcher will have to act in a technically creative fashion when doing the selection, thus a technical contribution is required based on some kind of logic, instead of arbitrariness (which is not deemed inventive in any field\textsuperscript{73}). Furthermore, what is needed is that the technical aspect, on which the selection will be based on, could presumably characterise all the members of the selected group\textsuperscript{74}. This could raise some questions as to the realism of the

\textsuperscript{67} Ibid., 243.
\textsuperscript{68} See Torremans, supra, 86.
\textsuperscript{69} ‘…empirical research industriously pursued may lead to a patentable invention’, Genentech, supra, 241.
\textsuperscript{70} See on this one also Williams v Nye [1980] 7 RPC 62; it was a case of mosaicking, where the combination of two similar machines operating related functions in order to establish a new use, was found lacking inventiveness.
\textsuperscript{71} See section of novelty on selection patents .
\textsuperscript{73} Sandvik Intellectual Property AB v Kennametal UK Ltd [2011] EWHC 3311, 185.
requirement, as well as to the requirement of ‘fair assumption’\textsuperscript{75}, since both promote uncertainty with regards to the assessment of the existence of inventive step.

3.2. Assessing the Evidence of Inventiveness- The case of Secondary Evidence

In order to make its decision, the Court, may rely on secondary evidence, which have the function of providing support for the claim of non-obviousness. For the purposes of this essay, we shall examine the case of commercial success, which is inextricably connected with the long-felt want argument.

3.2.1. Long-felt-want

The implications of this argument are quite clear; it essentially bears the logic that the solution proposed by the claimant/patentee is non-obvious, because if it had been obvious, then it would have been invented earlier so that this long-felt-want of the people and the society could have been satisfied. Even though long-felt-want can be claimed at any time, its evaluation must be careful\textsuperscript{76}. That is because it is merely an indication as to why the solution had not been given by someone else at an earlier stage. In that regard, case-law has structured some elements, functioning in a merely indicative way, such as the length of time that the particular need has been known or the extent to which materials and subsequent information used as the premises of the proposed solution had been available\textsuperscript{77}.

3.2.2. Commercial Success

Commercial success has been used as an argument to support non-obviousness on the basis that it fulfils a long-felt-want and because of this the proposed novel solution will enjoy commercial success, which consequently means that there was an inventive step when constructing the novel solution that the public warmly welcomed\textsuperscript{78}. There are three main reasons why an argument of this kind is hard to work: first, commercial success is nowadays especially, a matter of advertising and distribution. Especially in the

\textsuperscript{75} See Torremans \textit{supra}, 87.
\textsuperscript{76} Lionel Bently, \textit{supra}, 505.
\textsuperscript{77} Mentioned in Adolf Schindling/Illuminating device, T324/94 [1997] EPOR 146.
\textsuperscript{78} Samuel Parkes & Co v Cocker Brothers Ltd [1929] 46 RPC 241, 248.
pharmaceutical and medical sector, where there is very effective distribution behind\textsuperscript{79}, it becomes more visible that acclamation by the public does not come on its own. Second, the test of obviousness bears a question of a technical nature, not a commercial\textsuperscript{80}. Third, let us not forget that commercial success can only be evaluated as secondary evidence; therefore it has no further significance besides that\textsuperscript{81}.

3.3. Assessing the Patentability Requirements for partially-new inventions

After discussing all relevant aspects of the subject under examination, we need to go ‘back to basics’ in this chapter in order to explain the rationale of the patent system and the reasons why if something is new \textit{in part} but involves a clear inventive step and fulfills a long-felt need is not necessarily patentable. It was explained in Chapter II that, when something is partially new, it does not follow that it will be necessarily considered novel in its entirety. And that is fair. The justification for that will be revealed in the sequence of the following thoughts:

Patents create monopolies, so, even by definition they create market distortions\textsuperscript{82}. In that sense, one should be careful when interpreting the rules granting patentability so as to keep market distortions at the minimum possible level without, of course, limiting the scope of patent law in a disproportionate way.

The sectors that have raised most issues regarding products/processes that are partially new are two and they sometimes coincide: pharmaceutical/medical and chemical. Especially with regards to the first one, some definitions are in place. In order to understand the implications of partially new patents in the pharmaceutical sector, one would have to make reference as to how the pharmaceutical sector works. For our purposes, we need to identify between two main groups of pharmaceutical companies: originators or innovators and generics\textsuperscript{83}. The first ones are those who invest funds in R&D and apply for drug patents. As for the second ones, they come into play after the patents of the originators have expired; they manufacture

\textsuperscript{79} As noted in Barry Bleidt, “Recent Issues and Concerns about Pharmaceutical Industry Promotional Efforts” (1992) 22(2) Journal of Drug Issues 413, in many cases marketing costs exceed even R&D costs in the pharmaceutical industry.

\textsuperscript{80} Moehlycke AB v Procter & Gamble Ltd (No. 3) [1990] RPC 498, 503, as seen in Torremans, supra, 85.

\textsuperscript{81} Beloit Technologies Inc v Valmet Paper Machinery Inc [1995] RPC 705.

\textsuperscript{82} Jones Alison and Sufrin Brenda, \textit{EU Competition Law}, 4\textsuperscript{th} edition, Oxford University Press, 2011, 709-711.

the previously patented drugs and distribute them to the market at a fraction of the cost\textsuperscript{84}. The Commission’s recent Pharma investigation\textsuperscript{85} was initiated due to competition concerns between these two groups. In specific, the Commission was concerned that originators engage in methods of patent evergreening\textsuperscript{86} (by applying for second patents, selection patents and the like) that restrict market access to both generics and other originators, thus resulting in a negative overall impact on society and consumers, who would not be able to have access to cheaper generic drugs once the original patents expired\textsuperscript{87}. Besides the obvious problem of remonopolising previous art (which is mostly the case with selection patents\textsuperscript{88}), another, more important issue is created, considering the ‘abusive’ practices of evergreening that originators engage in. This problem is not merely restriction of competition per se, but the implications of this restriction on society\textsuperscript{89}. In specific, if in any case partially new processes/products are capable of being granted patentability in the sectors in question (no matter if they involve a clear inventive step or not), then originator companies could have a free ticket to evergreening. That would consequently mean that generics would not be able to come into play and hence, prices for drugs would remain high to the detriment of consumers and in general, society. This is a big issue, especially considering the importance of health and accessibility to drugs\textsuperscript{90}.

\textsuperscript{84} Ibid.
\textsuperscript{86} Supra, 615; When talking about generics, he states that they mostly want to evoke patents of innovators ‘variously described as “secondary”, “evergreening” or “life-cycle” patents. These patents do not protect the active ingredient that makes the drug effective as a treatment, but instead protect different physical forms of that drug, for example: different salts of the drug; dosage regimes; formulations; delivery devices and further medicinal uses’.
\textsuperscript{87} In order to understand the significance of the issue better see Johnson & Johnson and Novartis Case where the Commission fined the two companies for infringement of art 101 TFEU because they agreed with a generics company in the Netherlands that the latter would abstain from bringing the patented drug for the treatment of cancer after their patent expired, see Press Release http://europa.eu/rapid/press-release_IP-13-1233_en.htm, found in EU Focus, Johnson & Johnson and Novartis fined for delaying market entry of pain-killer, EU Focus 2014, 316, 6.
\textsuperscript{88} This is why, novelty should be, generally, given to those selections that entail restricted examples from the wider class which had not been tested or used before; in this way, no remonopolisation occurs, Catherine Colston and Jonathan Galloway, supra note 30, p 180-184
\textsuperscript{89} For a thorough analysis see Steve D. Shadowen, Keith B. Leffler, Joseph T. Lukens, Bringing market discipline to pharmaceutical product reformulations, IIC 2011, 42(6), 698-725.
On the other hand, especially because these industries play an important role as to whether and to what extent society will benefit, making patentability a very hard case (as it has become especially after the Genentech case in terms of inventive step), would create losses in the long-term. These losses will be borne by both the industries themselves – because they wouldn’t get any fair returns on their previous investments resulting in discouragement of further research\(^91\) - and the society – because if industries stop investing in research, then losses will be incurred in terms of possible benefits stemming from developments in the respective industries. That is in addition to the fact that “Patents are pivotal to the research-based pharmaceutical industry, given the enormous investment and risk required to develop innovative medicines. It can cost 1 billion or more to develop a new medicine in the period between discovery and marketing, normally a duration of 12 to 13 years. Only around 20% of new products ever recover the cost of development.”\(^92\) Furthermore, if patentability becomes very hard to prove, innovation will be impaired significantly, because it is the originators that both promote research and innovation via their patents and – usually – engaging in patent evergreening\(^93\); if they cannot have a fair access to patentability, then there will be nothing for the generics to provide to the market, as the latter do not engage in R&D\(^94\).

From this aspect, there will be further losses. Notwithstanding subsequent EU policy concerns that have to do mainly with the disadvantaged position of EU pharmaceuticals in comparison to American ones (and that would possibly constitute an incentive in order to grant patentability on less strict terms)\(^95\), given the above, it is up to the courts to decide to what extent the anti-competitiveness of a patent is harmful and needs to be revoked (or not be granted in the first place, at least in the UK). In that way, a line between patentability and non-patentability will be drawn. In that regard, there is usually a fairly good reason why some ‘inventions’ (in the broad sense) in these sectors, when partially new, are not considered novel.

\(^91\) Amanda Odell-West, ‘A proposal to amend the medical exclusion within patent law to provide for the patentability of certain methods of treatment’, E.I.P.R. 2007, 29(12), 492-499.
\(^93\) Carlos M. Correa, ‘Efforts to raise the bar in patent examination need to be supported,’ IIC 2012, 43(7), 747-750, who claims that the bar to patentability should be raised talks about relevant initiatives undertaken mainly in Brazil and Australia.
The balance between competition concerns and patent rights of course, is not conducted only by the courts, but primarily by the law itself. Since this is the rationale of the law, it would be outside the scope of both competition law and patent law to assume that in any case that something is new in part as long as it fulfills a long-felt-want and the inventive step is clear, patentability can be granted.

4. CONCLUSIONS

It has become by now obvious that the question of whether partially new solutions/products/processes can be granted patentability is a difficult one. It is not merely a matter of strict provisions that are applied automatically regardless of the case. To the contrary, partially new ‘inventions’, because of this special feature they have, ie that they are not entirely new, should be considered on a case-by-case basis. This argument is supported by the fact that the industries that claim patentability for partially new inventions are crucial not only for the preservation of competition, but also – and most importantly – for the welfare of consumers and society at large. A free ticket to patentability should not be given. In that sense, and taking into consideration all of the implications of patentability in the sectors-in-question, a better balance should be sought between raising the stakes too high for the inventive step, on the one hand (as proven after Genentech), and having the stakes too low for patentability in general (in the sense that something partially new could be granted patentability as long as the inventive step requirement is fulfilled) when it comes to products/processes that are partially new.