The protection of second therapeutical use inventions in the practice of the European Patent Office

La tutela delle invenzioni di secondo uso terapeutico nella prassi dell'Ufficio europeo brevetti

Emanuela Arezzo [*]

ABSTRACT:

The paper addresses the issue of patenting inventions for new therapeutic uses in the light of the legal framework provided by the European Patent Convention and the case law of the EPO Technical Boards of Appeal. The patenting of new uses of a known compound is, especially in the pharmaceutical field, an essential lever to promote innovation. In recent years, the EPO has adopted an increasingly "accommodating" attitude towards this type of findings, clarifying that the new therapeutic application is not to be confined to the treatment of a new ailment, different from the one cured by the previous use of the compound, but may well target the very same technical problem (i.e. the cure of the same disease). Thus, protection (in the form of new therapeutic use inventions) has been granted to findings aimed at modifying the form of administration of the drug or its dosage, at changing the functioning of the drug at a physiological or cellular level, or even validating the use of the therapeutic treatment for a new class of patients with different characteristics. Given this new expansionist drift of protection, however, many knots remain to be unravelled. In particular, a clarification would be needed with regard to the perimeter of exclusivity attributed to inventions of new therapeutic use, which should be considered as product inventions limited to the specific field of use, but whose structure is generally identical to that of other inventions that insist on the same molecular composition.

Keywords: patent – first therapeutical use – second therapeutical use – purpose-bound product protection.

[*] Associate Professor of Law, University of Teramo, School of Law; e-mail: earezzo@unite.it.
This contribution will be published in a volume dedicated to Prof. Vincenzo Di Cataldo.

Il saggio affronta il tema della brevettazione delle invenzioni di nuovo uso terapeutico alla luce del quadro normativo disposto dalla Convenzione sul Brevetto Europeo e della giurisprudenza delle Commissioni tecniche dei Ricorsi dell'UEB. La brevettazione dei nuovi usi di un composto noto rappresenta, specie in campo farmaceutico, una leva essenziale per promuovere l'innovazione. Negli ultimi anni l'UEB ha adottato un orientamento sempre più "accomodante" verso questa tipologia di trovati, chiarendo che la nuova applicazione terapeutica non va intesa come sinonimo di trattamento di una diversa patologia rispetto a quella per cui il precedente impiego del composto offriva una cura, bensì può ben risolvere il medesimo problema tecnico, apportando delle varianti all'idea di soluzione che la rendano originale. Sono stati così protetti, come nuovi usi terapeutici, trovati tesi a cambiare la forma di somministrazione del farmaco o il suo dosaggio, a mutare il funzionamento del farmaco a livello fisiologico o cellulare, o ancora a validare l'impiego del trattamento terapeutico per una nuova classe di pazienti con diverse caratteristiche. A fronte di questa nuova deriva espansionistica della protezione, molti nodi restano tuttavia da sciogliere: in primis, chiarire quale sia il perimetro di esclusività attribuito dalle invenzioni di nuovo uso terapeutico, che andrebbero considerate invenzioni di prodotto limitate allo specifico campo d'uso, ma la cui struttura è di regola identica a quella degli altri trovati che insistono sulla medesima composizione molecolare.

***Parole chiave**: brevetto – primo uso terapeutico – secondo uso terapeutico – protezione del prodotto limitata ad uno specifico uso*

TABLE OF CONTENTS:

Introduction.

It is very well known today that innovation in the twenty-first century tends to exhibit a cumulative and incremental feature. Technological progress often proceeds through small steps instead of major breakthroughs, giving birth to inventions which often do not lead to the introduction of entirely new products, but rather provide ameliorated features of existing ones, for example

improving the technical performances of a certain production process or eliminating a side effect of a product (ex. a medicinal one).

The incremental nature of innovation has significant repercussions and implications from the perspective of patent law. And in fact sequential innovation, flourishing on the trail of previous ones, normally produces a flow of what patent lawyers and academics refer to as "derivative" or "follow-on" inventions [1]: meaning technical solutions whose conception has been possible thanks to the implementation of a teaching (often a portion of it) embedded in a previous invention (hence, in most of the cases, already subject to patent protection) [2].

Under the taxonomy of "derivative inventions" academics and courts have with time developed several sets of sub-categories, each with different features, according to the type and degree of intensity of the "borrowing" from the previous patented teaching. Whereas "improvement inventions" probably represent the most well-known category of derivative inventions [3], scholars have framed the notion of "combination inventions" and "translation inventions" to describe scenarios where the inventive result comes from the com-

[1] The literature on the matter is abudant. See, *inter alia*, S. SCOTCHMER, *Innovation and Incentives*, The MIT Press, Cambridge, Massachusetts, London England, 2004. S. SCOTCHMER, *Protecting Early Innovators: Should Second-Generation Products Be Patentable?*, in *The RAND Journal of Economics*, 117, 1996; K.W. DAM, *The Economic Underpinnings of Patent Law*, in 23 *J. of Legal Stud.*, 1994, 247; J.B. KOBAK, *Intellectual Property, Competition Law and Hidden Choices Between Original and Sequential Innovation*, in 3 *Va. J.L. & Tech*., 6, 1998; R. GILBERT, C. SHAPIRO, *Optimal Patent Length and Breadth*, in 21 *Rand J. Econ.*, 1990, 106; P. KLEMPERER, *How Broad Should the Scope of Patent Protection Be?*, in 21 *Rand J. Econ.*, 1990, 113.

[2] The academic literature has implemented a vast set of terminology to refer to this dicothomy. See P. GRECO, P. VERCELLONE, *Le invenzioni e i modelli industriali*, Turin, Utet, 1968, at 100 distinguishing between main inventions and derivative inventions; N. GALLINI, S. SCOTCHMER, *Intellectual Property: When is the Best Incentives System?*, in 2 *Innovation Pol'y & Econ.*, 51 (2002), at 65 and ff., distinguishing between first generation and second generation patents; R.P. MERGER, R.R. NELSON, *On the Complex Economics of Patent Scope*, in 90 *Colum. L. Rev.*, 841, 1990, at 860, distinguishing between "broad/dominant" and "subservient" patents.

[3] H. AHN, *Second Generation Patents in Pharmaceutical Innovation*, Baden-Baden, Nomos, 2014, at 30, describing improvement inventions as inventions that build upon a basic invention. P. GRECO, P. VERCELLONE, (nt. 2), at 100, defining improvement inventions as those employing the same structural features of the main invention and staying within the same field of action. Also see V. FALCE, *Profili pro-concorrenziali dell'istituto brevettuale*, Milan, Giuffrè, 2008, at 249, underlying that improvement inventions focus on the same technical problem of the first generation patent (or a closely related one), in the attempt of ameliorating its overall performance.

bined use of two or more technical teachings – sometimes simply some technical features – already contained in two or more previously patented inventions [4] or where the technical contribution of the invention consists in the transposition of a known inventive concept to a different technical field where it will achieve a different technical effect [5]. Hence, the peculiarity of this latter sub-group of derivative invention is given by the fact that the claimed (derivative) invention is identical, in its structural features [6], to the one claimed in a previous patent, but its transposition to a different field makes it capable of solving a distinct technical problem [7].

Another kind of derivative inventions which has recently gained relevance concerns so called "selection inventions", described in the literature as "[…] an invention that has a particular concept which is selected from a prior broader or larger generic concept of an invention and that presents superior or advantageous properties compared to the broader concept, which were not disclosed in the prior art [8]". The peculiarity of this group of derivative invention

[4] More specifically, the inventive teaching comes from the bringing into light of specific correlations between elements contained in previous patented inventions, capable of producing new technical results. See P. GRECO, P. VERCELLONE, (nt. 2), at 103.

[5] According to Rivolta, the constituent element of a "translation" invention are: i) the shift of the invention to a different technical sector (from the one claimed in the first patent); ii) the solution of a different technical problem, brought about as a consequence of such a shift; iii) some degree of technical progress stemming from the aforementioned solution of a different technical problem. G.C.M. RIVOLTA, *La c.d. invenzione di traslazione nella dottrina italiana e straniera*, in *Riv. dir. ind.*, I, 1962, 5, at 8. Concurring on the need of the transposition to a different technical field is Di Cataldo. See V. DI CATALDO, *I brevetti per invenzione e per modello di utilità. I disegni e modelli*[3], Milan, Giuffrè, 2012, at 180, drawing such definition from the wordings of the Italian jurisprudence.

[6] Some authors in the past, however, would not deem the mere act of transposing the invention to a different technical field enough to claim a new invention, asking for further adaptation or modification of the inventive concept in order for it to obtain patent protection. See M. ROTONDI, *Diritto industriale*[4], Milan, Ambrosiana, 1942, at 177 and ff.

[7] See T. ASCARELLI, *Teoria della concorrenza e dei beni immateriali*[3], Milan, Giuffrè, 1960, at 553 and ff.; P. GRECO, P. VERCELLONE, (nt. 2), at 101, making the example of a instrument for technical design implemented to draw a parabola, which is later on implemented to make a cannon viewfinder. V. DI CATALDO, *Sistema brevettuale e settori della tecnica. Riflessioni sul brevetto chimico*, in *Studi in onore di Giuseppe Auletta*, vol. I, Milano, Giuffrè, 1988, 113, at 185, explaining that the novelty and inventiveness of such inventions must be assessed with regard to the act of transferring the inventive concept from one sector to another (and not with regard to the inventive concept itself which is obviously the same one).

[8] See H. AHN, (nt. 3), at 30-31, adding that the peculiar feature of such invention is that selection invention fall under the scope of the prior art disclosure, but it has not been individually disclosed in the prior art.

is therefore given by the circumstance that they solve a new technical problem by phishing out technical elements *vaguely* disclosed in a previous patent, and finding new useful properties not outlined before [9]. Hence, the derivative nature stems from the circumstance that the first patent contains and discloses part of what will be the content of the future patent, but only in general and broad terms [10].

While, as hinted, the above categorization stems mainly from scholars and jurisprudence, there is only one type of derivative invention whose patentability has been expressly recognized in statutory provisions in the European Patent Convention and, as a consequence, into the law of its adhering Countries: namely, second use inventions pertaining to the medical field [11], as disciplined into Art. 54, 4° and 5°, EPC 2000. This contribution is dedicated to this particular type of inventions. It will study how the discipline of first and second medical use invention has evolved in the years, from the early jurisprudence of the EPO Board of Appeals, to the latest amendments of the EPC, allowing for an extremely broad expansion of the realm of patentable subject matter. It will be eventually asked what drawbacks, if any, such an expansion is likely to assert in the pharmaceutical sector.

---

[9] Cfr. *Diastereomers*, T12/81, 1982, in *OJ EPO*, 1982, 296, at 301, § 11 of the R.D., explaining that "The concept of substance selection presupposes the choosing of a single compound or a specific sub-group from a group of substances".

[10] And indeed, as a general rule, the narrower the selection is with regard to the generic terms used in the main patent, the more likely the selection will be deemed new and the protection granted. See B. DOMEIJ, *Pharmaceutical Patents in Europe*, Norsterdts Jurick Stockholm, Kluwer International Law (The Hague), 2000, at 112.

[11] It is appears interesting mentioning that some signatory Countries of the EPC have chosen to implement this provision broadly, with no explicit limitation to the field of medicine. Already in 1979, when the EPC 1973 limited protection only to the first therapeutical use of a substance known to the art because of a previous application in a non-medical field (art. 52, 4°, EPC 1973), Italy amended art. 12 of its national patent law (at that time R.D. 29 June 1939, n. 1127) introducing a fourth prong allowing patentability of a substance or composition of substances already known to the state of the art, in light of a new way of employment. This provision has opened the way to patentability of all substances (known to the state of the art) in light of a newly discovered use, but regardless of the technical field both of the first product patent on the substance and of the second medical use invention. In other words, according to this regime second use inventions are simply protectable in all field of technology. See, for all, V. DI CATALDO, *I brevetti per invenzione e per modello di utilità*, (nt. 5), at 160 and ff.

1. *Origin of the problem: second use patents in the chemical field.*

Second use inventions fall into the category of derivative inventions because they consist in the discovery of a new purpose or use of a product which has been already patented for a different employment [12]. In some way, they can be deemed as a new version of translation invention described above, where the inventor explores the technical teaching already protected by a patent trying to conceive further useful ways of employment of the invention in a different technical field or, in this case, even in the same one [13].

Comprehensibly translation inventions in industries like textiles and mechanics, the ones patent law was originally shaped for [14], did not proliferate. This is mainly due to the fact that in these sectors, the mode of employment of the (mechanical) product was (and still is) intrinsically linked to its structure, hence, automatically revealed by the inventor with the very same act of disclosing the invention and highlighting its advantages over the prior art in the solution of the prospected technical problem [15]. Moreover, because of this stringent link with its structural features, the mode of employment of a given mechanical invention tended to be (and generally is) just one [16].

Research in the chemical field challenged all the above assumptions. In chemical inventions, the technical features of the claims teach us what its constituent elements are and what is the chemical structure, but structure alone does

---

[12] See G. SENA, *I diritti sulle invenzioni e sui modelli ornamentali*[4], in *Trattato* Cicu-Messineo, Milan, Giuffrè, 2011, at 322.

[13] In this sense V. DI CATALDO, *I brevetti per invenzione e per modello di utilità*, (nt. 5), at 161; A. MUSSO, *Brevetti per invenzioni industriali e modelli di utilità*, in *Commentario cod. civ. Scialoja-Branca*, Bologna, Zanichelli, 2013, at 197 e 213; G. GHIDINI, *Profili evolutivi del diritto industriale, Innovazione – Creatività – Informazione, Dinamiche conflittuali, esperienze di condivisione*[3], Milan, Giuffrè, 2015, 123.

[14] See V. DI CATALDO, *Sistema brevettuale e settori della tecnica*, (nt. 7), 113, at 117 and ff., explaining that the patent system reflects the features of the economic sectors emerging during the industrial revolution, at the time it was framed. The spreading of different industrial sectors later challenged some of its rules and demanded for some rethinking.

[15] See G. PATERSON, *The Novelty of Use Claims*, in 27 *I.I.C.*, 179, 1996, at 181. Similarly on this point: A. MUSSO, (nt. 13), 196, explaining that mention of use within electro-mechanic inventions was superfluous as it was deductible from the very same function of the machine, as disclosed in the description of the invention.

[16] Cfr. G. FLORIDIA, *Procedimento e prodotto nelle invenzioni farmaceutiche*, in *Riv. dir. ind.*, I, 1988, 46, at 48; V. DI CATALDO, *Sistema brevettuale e settori della tecnica*, (nt. 7), 113, at 156 and ff.

not tell anything about what the chemical substance does [17] nor does it give us any suggestions about how it could be used or implemented [18]. Furthermore, experience in the field soon showed that chemical compounds and substances were often found to have several properties, hence were capable of multiple practical applications. The question therefore arose about what protection, if any, had to be granted to secondly conceived uses of a chemical compound already patented in light of a certain first property outlined by the inventor, given that there was indeed a widespread agreement at that time – much cherished by the EPO Chambers – that intended the concept of absolute (patent) protection for product inventions not simply to mean that protection would cover the product regardless of the way it had been manufactured, but also that protection would extend to each and every conceivable mode of employment of the claimed invention, even to the ones not envisioned by the patentee at the date of filing [19]. The issue, therefore, regarded whether independent patent protection for second use inventions was conceivable or rather whether the new further applications would automatically fall into the scope of protection of the first patent [20].

---

[17] It is worth recalling, at this regard, the words of the Italian Supreme Court who vividly clarified that in the chemical field the invention does not lay in the mere formulation of a molecular structure, but rather in the end product which can be manufactured through the employment of the claimed substance in light of its properties. See Italian Supreme Court (Cass. Civ., I Sez.), judgement n. 2575, 6th March 1995; Italian Supreme Court (Cass. Civ., I Sez.), 16.11.1990, n. 11094 (Cimetidine case), published in *Nuova giur. civ. comm.*, I, 1991, 545.

[18] See G. PATERSON, *The Novelty of Use Claims*, (nt. 15), at 181.

[19] See V. DI CATALDO, *I brevetti per invenzione e per modello di utilità*, (nt. 5), at 156 and ff. The author, however, argues that such a rule needs important rethinking especially with regard to the part implying protection against all unforeseen uses of the invention, despite not being claimed nor disclosed, as such theorization stems from the framing of the patent system in light of the features of mechanical sector where it is very rare that a product invention is capable of different uses than the ones conceived by the patent holder. See V. DI CATALDO, *Tra tutela assoluta del prodotto brevettato e limitazione ai procedimenti descritti e agli usi rivendicati*, in *Riv. dir. ind.*, I, 2004, 111, at 115. A similar opinion has been expressed by P.H. EGGERT, *Uses, New Uses and Chemical Patents, a Proposal*, in 1968 *Wis. L. Rev.*, 901, 1968, at 913 vividly arguing that "it is only because an additional, nonobvious use is unlikely for a mechanical device that such statement as «a patentee is entitled to every use of which the invention is susceptible […] known or unknown» became acceptable doctrine" (quoting In re Thuau, 135 F.2d 344, 347 (C.C.P.A. 1943).

[20] And indeed there is still a widespread consensus that chemical patents claiming a *new* structure of a compound receive "absolute" protection in the above twofold meaning. See H. AHN, (nt. 3), at 33 and 51. B. DOMEIJ, (nt. 10), at 127. S.J.R. BOSTYN, *Patenting DNA Sequences (Polynucleotides) and Scope of Protection in the European Union: An Evalutation,*

Despite sound reasons existed to introduce protection for second use inventions in the chemical field, significant hurdles also existed. The first obstacle regarded a presumed lack of novelty, as the structural portion of the second use invention is entirely claimed by a previous patent (or patent application), a circumstance for a long time claimed to destroy the novelty of this kind of derivative inventions. Also very controversial was the issue regarding the breadth of main and derivative patents in this case and, consequently, infringement [21].

Given the complexities surrounding patentability of second use inventions in the chemical field, the EPC 1973 framers decided not to address the issue in general terms and restricted their attention to the sole instance of subsequent applications of substances and compositions known to the state of the art where the new way of employment pertained to the medical field. Protection of second use inventions in the medical field, however, was not immediately granted to all inventions of this kind. On the contrary, the EPC 1973 only offered protection to inventions bringing into light a first theraputical use of a substance or composition already known to the art pursuant to a different employment in a different (*read:* non medical) field [22]. To better understand the *rationale* of Art. 54, 5° prong of EPC 1973, it needs to be put in context.

2. *The codification of protection of "first" use inventions in the medical field …*

Patentability of pharmaceutical products has always been a rather thorny issue because the classical *rationale* of incentivising research and technical progress in the field throught the instrument of exclusive rights had to be balanced against a social public interest possibly higher in rank: namely, the protection of public health and the rights of individuals to (affordable) access to the best and more advanced medicaments and treatments [23].

Luxembourg, European Commission, 2004, at 56-66. In favor of absolute protections of chemical compounds see also *Lundbeck v. Generics Ltd*, [2008] EWCA Civ. 311, § 54.

[21] See at this regard R. MOUFANG, *Use and purpose indications in patent claims*, in *OJ EPO*, Special edition, 1, 2011, 116, at 117 and ff., reporting that still today there's not in Europe a uniform interpretation regarding patent breadth of claims containing use or purpose limitations.

[22] The provision indeed used to (and still does) conceive(s) patentability of "[…] any substance or composition, comprised in the state of the art, for use in a method referred to in Art. 52, 4° EPC [today Article 53(c)], provided that *its use for any such method* is not comprised in the state of the art (italics added)". See *infra* at the end of this paragraph.

[23] See S. JOSEPH, *TRIPS and the Right to Health*, in ID., *Blame it on the WTO? A human*

With such difficult balancing of interests in mind, EPC framers introduced in Art. 52, 4° of the EPC 1973 a strict ban (still in force today) against patentability of therapeutic, diagnostic and surgical *methods* to be used in the human or animal body, on the ground that such subject matters could not be considered inventions susceptible of industrial application pursuant to art. 52, 1° EPC [24]. The lack of exclusive rights on such *methods* indeed was meant to spur the dissemination of the most advanced medical techniques [25], while at the same time protecting physicians' freedom to choose the most appropriate treatment for their patients [26]. Within the delegations, however, some lamented

rights critique, Oxford, Oxford University Press, 2011, 214-244, esp. 230 ff. See also K.C. SHADLEN, B.N. SAMPAT, A. KAPCZYNSKI, *Patents, trade and medicines: past, present and future*, in *Review of International Political Economy*, 27, 2020, 1, 75-97; O. AGINAM, J. HARRINGTON, P. YU (eds.), *Global Governance of Hiv/Aids: Intellectual Property and Access to Essential Medicines*, Cheltenham UK-Northampton, MA, USA, Edward Elgar Publishing, 2010.

[24] Note that art. 52, 4° EPC 1973 has been replaced today by art. 53(c) EPC 2000) which classify therapeutical methods as exceptions to patentability. Indeed, as explained by the EBOA in *Diagnostic Method*, whilst the legislator had chosen to impede patentability by recurring to a legal fiction of lack of industrial applicability, "[…] the exclusion from patentability of the above-mentioned methods under Article 52(4) EPC seems actually to be based on socio-ethical and public health considerations. [As] medical and veterinary practitioners should be free to take the actions they consider suited to diagnose illnesses by means of investigative methods". Cfr. Decision G 1/04, *Diagnostic Method*, in *O.J. EPO*, 2006, 334, r.d. § 4. At this regard see J. PILA, *Article 52(2) of the Convention on the Grant of European Patents: What did the Framers Intend?*, in 36 *IIC*, 2005, 755-787, arguing that the gradual acknowledgment of this lead to the change into the text of the EPC. See, however, also R. KRAßER, *Purpose and Limits of the Exclusion from Patentability of Medical Methods, Especially Diagnostic Methods*, in *Patent and Technological Progress in a Globalized World,* Liber Amicorum *Joseph Straus*, M.J. Adelman, R. Brauneis, J. Drexl, R. Nack (eds.), Springer, 2009, 275, arguing that the link of the patent ban on medicinal procedures with the requirement of industrial applicability was already recognized by the members of the 1973 Munich Diplomatic Conference as being systematically incorrect. Patentability of medical treatment methods is recognized, on this ground, in Australia. A. SIMS, *The case against patenting methods of medical treatment*, in *E.I.P.R.*, 2007, 43.

[25] Cornish and Llewelyn refer to public policy considerations aimed at favouring the dissemination of new medical techniques unimpeded by claims to exclusive rights. See W. CORNISH, D. LLEWELYN, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*[6], London, Sweet & Maxwell, 2007, 222.

[26] Many authors agree that the goal of the provision was to shield physicians' freedom of operation from the risk of patent infringement. See J. MEIER, *European Patent Office*, in *Patent Protection for Second Medical Uses*, J. Bühling (ed.), AIPPI, 2016, Kluwer Int., The Netherlands; J. COCKBAIN, S. STERCKX, *Purpose-limited pharmaceutical Product Claims under the Revised European Patent Convention: A Camouflaged Attack on Generic Substitution?*, in *Intellectual Property Quarterly*, 2010, 88, at 88; D.R. SCHNEIDER, *Patenting of Pharmaceuti-*

the discriminatory nature of the ban, depriving only the medical sector from process claims, available for all other technical fields. For this reason, the signatories of the EPC contextually introduced, by way of an exception to the exception, the possibility to patent "products, in particular substances or compositions, for use in any of these methods" (art. 52, 4°, EPC 1973, last indent). This to make sure that products, such as medicaments, and substances used in medical treatments – for example vaccines – would not be touched by the exception and could benefit from patent protection [27].

Even this latter scenario, however, was not deemed entirely satisfactory. In such a framework, indeed, *new* compounds and substances, specifically conceived for a medical purpose, would receive protection as product inventions. No protection, however, seemed available for inventors whenever they would come up with a new and inventive medical application of a compound which was already known to the state of the art (think for example of a chemical substance previously patented in light of its hydrating properties, hence for cosmetic purposes, later found to also cure eczemas). Such cases, which were quite frequent in the industry, presented several hurdles to overcome. As mentioned, the invention could not receive protection in the form of product patent, as it would lack (structural) novelty [28], nor could it be claimed exclusively throughout a use claim, as this claiming format was generally equated to a process claim (a claim towards a certain abstract activity): hence it would fall into the ban against the patentability of methods in the medical field [29].

Once again the delegations of the contracting States split between those

---

cals – Still a Challenge?, in 39 *I.I.C.*, 2008, 511, at 512. F. BENUSSI, *Sulla brevettabilità della seconda indicazione terapeutica nella prima decisione della Commissione ampliata di ricorso*, in *Riv. dir. ind.*, II, 1985, 103, at 112. This interpretation has also been espoused by the EBOA in the *EISAI* decision where it stated that the intention of art. 52(4) of the EPC (1973) was only to "[…] free from restraint non-commercial and non-industrial medical and veterinary activities". See *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 22. *Cygnus/diagnostic measure*, G 1/04, 2006 E.P.O.R. 15, 161.

[27] See E.D. VENTOSE, *Patent Protection for second and further medical uses under the European Patent Convention*, vol. 6, n. 1, 2009, SCRIPTed 57, 58. A. VANZETTI, V. DI CATALDO, *Manuale di Diritto Industriale*[8], Milano, Giuffrè, 2018, 386 and ff.

[28] As explained by G.D. Paterson, in 'normal' product claims, in order to positively assess novelty, the invention must contain at least one physical parameter which distinguishes it from the state of the art. By contrast, in the case of first and subsequent medical uses, the product *per se*, as defined in the claim, is identical to a former one, subject to patent protection. See G.D. PATERSON, *The Patentability of Further Uses of a Known Product under the European Patent Convention*, in 1 *E.I.P.R.*, 16, 1991, at 18.

[29] B. DOMEIJ, (nt. 10), at 127.

who supported the istances of the pharmaceutical industry [30], strongly asking for the recognition of second medical use inventions for all those inventions which would bring into light further medical properties of known compounds and substances, and those who embraced a more cautious position and wished for the introduction of an exception only with regard to the case of the discovery of a new therapeutical use of a substances known to the state of the art for its employment in a different technical sector [31]. In other words, much like the general conceptualization of translation inventions, where the novelty and inventiveness of the derivative invention had to be searched in the transposition of the inventive concept to a different technical sector, it was proposed to create an exception to the general rule granting absolute protection towards product inventions (such as chemical substances and compositions [32]) only in the case the new subsequent use happened to be in a different technical sector and the latter sector being the medical one. This second approach eventually prevailed and led to the insertion of a provision in art. 54 EPC (with regard to novelty) expressly allowing for "the patentability of any substance or composition*, comprised in the state of the art* […]" for use in a medical method, "[…] provided that *its use* for any such method *is not comprised in the state of the art*" (italics added) (Art. 54, 5°, EPC 1973).

The latter provision was groundbreaking in several respects. First of all, it codified for the first time protection to *use* patents into the norms of an international Convention. It is worth noting indeed that although *use claims* where contemplated by the Rules on implementations of the EPC1973 for all kind of inventions, they were conceived as procedural instruments to further illustrate the technical teaching of the invention, and not as a specific, stand-alone, category of inventions (like with product and process inventions) [33]. On the contrary, one might dare to say that art. 54, 5°, EPC 1973, codified almost a third

[30] See D.R. SCHNEIDER, (nt. 26), at 514, reporting that pharmaceutical companies asserted that economically second medical indications were often more significant than first medical indication patents.

[31] For an in-depth study of the *travaux préparatoires* see E.D. VENTOSE, *Patent Protection*, (nt. 27), 59-62.

[32] Indeed, it was very much shared at that time the idea that product protection for *new* chemical substances and composition patented in light of a medical application would grant absolute protection, in a way to cover all unforeseen medical application of the compound. See B. DOMEIJ, (nt. 10), at 127. This approach will be shared by the EPO chambers in the jurisprudence of the early eighties, as shown in the following paragraph. See, in particular, the *Hoffman La Roche/Pyrrolidine derivatives* case and decision G2/88 of the EBOA: see *infra* note 45 and 46.

[33] More specifically, use claims were treated as a type of process claim. See Guidelines for Examination, Part F, Chapter IV, § 4.16 (as revised in 2019).

type of inventions [34] – generally addressed to as *purpose-bound* product protection – where it envisaged a new form of *product* protection (as it clearly emerges from the references to "substance and composition" [35]), but limited in its scope by the claimed use in the medical field [36].

A second element worth of consideration regards precisely novelty. The provision – which has indeed been inserted in the norm dealing with the requirement of novelty of the invention – had the merit to expressly sanction that novelty (but it seems, for the sake of logical reasoning, also inventiveness) of second use patents (i.e. first medical use patent) ought to be scrutinized with regard to the newly claimed *use* [37], rather than the structural features of the (known) substance [38]. It codified therefore an exception with regard to the application of the novelty requirement to such category of inventions [39], whereas,

---

[34] Some authors have conceptualized second use inventions as a third type of inventions, respectively after product and process inventions. See G. SENA, (nt. 12), at 85 and ff., 144 and ff. But see *contra* G. FLORIDIA, *Sull'attuazione dei TRIPs: I brevetti*, in *Dir. ind*., 6, 1995, 550, at 551, arguing that such a theorization would be contrary to the patent framework enshrined in the TRIPs Agreement where art. 27, 1° prong, explicitly mentions only product and process inventions.

[35] Some authors have suggested that the explicit mention of just "substances and compositions" would seem to suggest not simply that second use patents were not conceivable for process inventions, but also that they were available only for a limited subset of subject matters falling into the categories of products invention, leaving out all other ones, such as for example medical instruments and devices. See E. VENTOSE, *No European patents for second medical uses of devices or instruments*, in *EIPR*, 11 et ff.; in a similar sense R. MOUFANG, *Patentability of pharmaceutical innovations: the European perspective*, in J. DREXL, N. LEE (eds.), *Pharmaceutical Innovation, Competition and Patent Law, a Trilateral Perspective*, Cheltenham UK-Northampton, MA, USA, Edward Elgar Publishing, 2013, 54, at 65. This was confirmed by the EPO Technical Board in decision T 227/91 of 15 December 1992, OJ EPO 1994, 491 – *Second surgical use/CODMAN*, where it was held that "the surgical use of an instrument was not analogous to a therapeutic use, since the instrument was not consumed in the application and could be used repeatedly for the same or even for further purposes".

[36] In this regard see R. MOUFANG, *Patentability of pharmaceutical innovations*, (nt. 35), 54, at 65.

[37] The provision expressly says "[…] provided that *its use* for any such method *is not comprised in the state of the art*", italics added.

[38] Harsh criticism was moved by C.M. Correa, arguing that patentability of such inventions is based on a "legal fiction of novelty". See C.M. CORREA, *Patent rights*, in C.M. CORREA, A.A. YUSUF (eds.), *Intellectual Property and International Trade: The TRIPs Agreement*^{2}, Wolters Kluwer, The Netherlands, 2008, at 238.

[39] See at this regard the Case Law of the BOA, § 7.1.1. where it states, commenting on art. 54, 4°, EPC, that such provision introduces "[…] in respect of substances and compounds used in surgical and therapeutic treatment and in diagnostic processes carried out on humans and

pursuant to general European patent law principles, the addition of a use indication within a normal product claim was not deemed enough to make such subject matter novel with regard to a piece of prior art disclosing the same product (*read* also the same substance) without such an indication or purpose of use [40]. But this is hardly the only point for which the kind of novelty requested by this article appears exceptional. And indeed not simply the provision shifted the focus of the novelty analysis from the structure of the compound to its claimed use, but it further conditioned the assessment of the requirement to the twofold conditions that i) the use pertains to the medical field and that ii) the compound or substance has never been used for medical purposes before (the provision reads: "[…] provided that *its use* for *any such method* is not comprised in the state of the art", italics added). Such rigid and absolute interpretation of novelty intended as transposition to a different technological field (from a non medical one to a medical one) was probably conceived simply to rule out protection of second medical use inventions in general.

3. *... and its drawbacks for the pharmaceutical industry.*

The groundbreaking effects of the above provision in the EPC 1973 were limited as hinted above, only to *first* therapeutic uses – later discovered – of a chemical compound or substance known for its mode of employment in a different technical sector, leaving out of protection subsequently discovered medical applications of both first medical use inventions but also of substances and compositions patented as product inventions pursuant to a first therapeutical application. For its part, the jurisprudence of the EPO Technical Boards of the early eighties seemed to interpret the scope of protection of first therapeutic inventions very broadly, with the consequence of leaving little room for independent protection of further medical applications, which were all deemed to fall within the scope of protection of the first medical use invention [41].

---

animals, a *special concept of novelty unknown in other technical fields*" (Italics added). Much in the same way, the Guidelines for Examination stress that "Art. 54(4) and (5) […] provide for *an exception* from the general principle that product claims can only be obtained for (absolutely) novel products". See Guidelines for Examination, Part G, Chapt. IV, § 7.1.

[40] And indeed while, as mentioned, use indications were admitted in the past, the addition of the wording "for use" within a product claim was not intended to limit the scope of protection exclusively to products intended for such specific use. R. MOUFANG, *Use and purpose indications in patent claims*, (nt. 21), 116.

[41] See *Hoffman La Roche/Pyrrolidine derivatives*, T 128/82, 1984, O.J. EPO, 164, 15 IIC 520 (1984), r.d. § 13, where the Technical Board addressing the issue of novelty in first thera-

In the well known decision *Hoffman La Roche/Pyrrolidine derivatives*, the Technical Board was confronted with the issue of how specific the claim towards the new therapeutic use should be, in order to overcome the hurdles set forth by the conjunct reading of Article 52(4) and Article 54(5) EPC 1973, and how such limitation should be interpreted, in terms of patent scope [42]. Interestingly, providing an interpretation that has later become established practice within the EPO jurisprudence [43], the Board concluded that despite a specific use in therapy is generally disclosed in the specification [44], this circumstance "[…] does not in itself call for a restriction of the purpose-limited product claim to that use" [45]. In the reasoning of the Technical Board, there would be no reason to discriminate, as far as the scope of protection is concerned, between an

peutical invention explained that "[…] Novelty […] is not only destroyed by the fact that the same specific therapeutic effect is already known to the art, but suffers also from the disclosure of *any other specific therapeutic application.* The *disclosure of any specific effect*, therefore, always has the same consequences as far as novelty is concerned; which in turn makes it fair to regard as admissible *a broad statement of purpose covering all and any specific indications"* (italics added). On this point see also R. MOUFANG, *Methods of Medical Treatment Under Patent Law*, in 24 *I.I.C.*, 1993, 18, at 19.

[42] Significantly, the examining division had refused patentability on the ground that a claim containing a mere reference towards pyrrolidine derivatives "as an active pharmaceutical substance" was not sufficient to overcome such hurdle, despite the circumstance that some of the claims of the invention (namely claims n. 3 and 4) were more specifically hinting at the substance's capability of being employed to combat cerebral insufficiency and to increase intellectual ability. The Board of Appeal came to a different conclusion stating that "substance and medical preparation claims for therapeutically active compounds not limited to specific indications are allowed" and that such claims will "[…] under Article 54(5) EPC [to] cover *the whole field of therapy"* (italics added). See *Hoffman La Roche/Pyrrolidine derivatives*, T 128/82, 1984, O.J. EPO, 164, 15 IIC 520 (1984), Summary of facts and submissions § I and II.

[43] The same conclusion was reached by the Board in *Roussel-Uclaf/Thenoyl peroxide*, T 36/83, 1985, O.J. 1986, 295, r.d. §§ 5.1.-5.2. More broadly, see Case Law of the Board of Appeals, 9th ed., 2019, section I (Patentability), § 7.1.2.

[44] And indeed at least one therapeutical use must be disclosed in the application to comply with Art. 54(4) EPC 2000 and disclosure of a general pharmacological effect should not be accepted. Cfr. *Serotonine receptor/ELI LILLY*, case T 241/95, 2000, O.J. EPO, 2001, 103, r.d. § 3.1.2., stating that "a pharmacological effect, cannot in itself be considered a therapeutic application." More extensively see D.R. SCHNEIDER, (nt. 26), at 520, adding that the disclosure of the medical use even in first medical use inventions should be specific, substantial and credible, as in all other technical fields.

[45] See *Hoffman La Roche/Pyrrolidine derivatives*, T 128/82, 1984, O.J. EPO 164, 15 IIC 520 (1984), headnotes, where it was clearly stated that "[…] Where a known compound is for the first time proposed and claimed for use in therapy, the fact that a specific use is disclosed in the specification does not in itself call for a restriction of the purpose-limited product claim to that use".

invention pertaining to a (structurally) *new* therapeutically active compound, whose protection would cover the whole field of therapy, notwithstanding the insertion in the specification of likely indications of use [46], and a therapeutically active compound whose structure was already known in the state of the art (although with relation to a different and non medical field). According to the Board, the principle of equal treatment, indeed, demanded that such broad protection be afforded also to first therapeutical use inventions which, for the first time, make a known compound – known in light of an application in a *non* medical field – available for therapy [47].

The consequence of this approach was that the initial discovery of one medical effect of a known substance was able to vest the patentee with a 'monopoly' over all future discoveries of new therapeutic effects [48]. At the end of the 1980s, however, the debate on the patentability of further medical indications became intense and demand for this type of protection much stronger [49]. As pharmaceutical research moved away from pure chemistry to life sciences, random synthesizing of thousands of new compounds to screen likely effects became a less efficient research strategy, and the industry became more focused on biological studies [50], inquiring on known correlation between (organic) chemical compounds and the biological effects produced [51].

---

[46] The principle of absolute protection for chemical substances was clearly stated by the Enlarged Board of Appeal in G2/88, 1990, OJ EPO 93, also published in 22 IIC 85, 1991. More extensively, see G.D. PATERSON, *Product Protection in Chemistry: How Important for the Protection of an Apparatus, Device or Substance Are Statements Made in a Patenta s to Their Purpose?*, in 22 *IIC*, 852, at 857 and ff.

[47] See *Hoffman La Roche/Pyrrolidine derivatives*, T 128/82, *supra*, r.d. § 10. The Board further explained that lacking an explicit provision in art. 54 stating that broad protection should not be granted, the usual treatment relating to new compouds should be followed.

[48] In this sense see E.D. VENTOSE, *Patent Protection*, (nt. 27), 63.

[49] In this sense also Galit Gonen in J. NURTON, *Roundtable: The second medical use challenge – full transcript*, in *Managing Intellectual Property*, 16 February 2017, 1. See also H. SUCHY, *Patent Protection for a Second Medicinal Use*, in 6 *E.I.P.R.*, 161, 1982, warning against the negative and economically unjustifiable outcomes the perceived ban on patentability of second medical uses would cause, as it would lead pharmaceutical companies to abandon promising lines of drug development and invest in the search of brand new molecules, whose patentability was not at risk.

[50] See B. DOMEIJ, (nt. 10), at 130 and ff. The author also reports as likely cause that ignited the debate on patentability of second medical uses the circumstance that after the Thalidomide disaster public authorities required more stringent investigations on adverse effects of pharmaceuticals, before they could be sold in the market. Therefore, such further studies and testing on the pharmaceuticals surely led to the discovery of further useful medical applications.

[51] See P.W. GRUBB, P.R. THOMSEN, T. HOXIE, G. WRIGHT, *Patents for Chemicals, Pharma-*

4. *The protection of second medical use inventions through "Swiss-type use claims".*

The loophole in the provisions of the EPC has been closed by the EBoA in seven parallel decision – the most famous being the *EISAI* decision – where it admitted protection of second medical use inventions claimed throughout so called "Swiss-type use claim" [52]. The latter was a new claiming format recently adopted at that time by the Swiss Federal Intellectual Property Office, in a statement of practice regarding use claims in general [53] and it was specifically meant to allow the patenting of inventions consisting in the use of a (known) substance or composition for the manufacture of a medicament for a specified (new) therapeutic application [54]. In other word, a peculiar form of process invention [55].

According to the EBoA, whilst a claim directed to the mere "use" of a substance for the treatment of the human or animal body by therapy had to be regarded "[…] as confined to the step of treament", hence not patentable, the "Swiss-type use claim" did not conflict with the prohibition contained in art. 52(4) EPC 1973 (today 53(c) EPC2000), as the invention was not conceived as a pure method claim, but as a *manufacturing* process claim [56], where prod-

---

ceuticals and Biotechnology, Oxford, Oxford University Press, 2017, at 264, explaining that today, in terms of promoting innovation, patentability of new indication of known medical compounds is extremely important since a new indication can be equally important to patients suffering from a certain illness as a new drug based on a new active ingredient.

[52] *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO 64-66, also published in *Riv. dir. ind.*, II, 1985, 103. The same judgement was rendered in other six decisions: *Bayer*, G 1/83, OJ EPO 1985, 64; Dr Karl Thomae, G 2/83; CIBA-GEIGY, G 3/83; Dr Karl Thomae, G 4/83; PHarmuka, G 6/83; CH Boeringer Sohn, G 7/83.

[53] See at this regard Legal Advice from the Swiss Federal Intellectual Property Office, O.J. (EPO) 1984, 581.

[54] *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 19. The constituent parts of a second use invention claimed through swiss type of claim format would be: a) the implementation of a known compound or substance; b) for the manufacture of a medicament; c) for a new medical purpose.

[55] It is worth noticing that in the North American patent system second use inventions fall into the category of process inventions. See 35 U.S. Code § 100(b) where it explains that "the term 'process'means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material". Moreover, second use inventions can be patented regardless of the technological field – hence, not limited to medical or chemical field. See at this regard P.H. EGGERT, (nt. 19), at 909 and ff., criticising the law for having granting protection only through a less vigorous means of protection, more challenging to enforce.

[56] The Board explained, indeed, that use claims can be regarded and treated as method claims,

ucts obtained thereby were meant to be employed according to a *new* and *inventive* therapeutic application [57].

As far as novelty was concerned, the EBOA recurred to analogic reasoning and declared that like in the case of first medical uses of known chemical compounds – where novelty for the medicament forming the subject-matter of the claim was derived from the discovery, for the first time, of a medical application, regardless of the circumstance that the structural composition of the compound was known – also in the case of subsequent medical uses it seemed reasonable to derive novelty from the *further* pharmaceutical use of the known substance, notwithstanding the fact that a pharmaceutical implementation of the substance was already known [58].

Obviously, the *EISAI* decision and the introduction by the EBoA of a new claiming format to protect second medical use inventions were not spared cricitisms for going against the spirit of the EPC [59] and for an overly broad construction of the novelty requirement, stretching its contours way to far [60]. Above all, the fictional construction of such claiming format, depicted as a *process* claim where the process itself was – in most of the cases – well known to the state of the art, raised several complexities regarding the actual scope of such

---

the only difference being that the sequences of steps is usually implicit within a use claim (where only the purpose of use is indicated), whereas it is set out explicitly (as passages to carry out the activity) in method claims. Therefore, according to the Enlarged Board, there would not be a substantial difference between the two claiming formats, the choice being just a matter of preference. See *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 11.

[57] *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, §18 (end of the paragraph). Claiming the invention as manufacturing process also proved helpful in demonstrating its industrial application. *Id.*, § 16. And indeed it is worth to remember that method of treatment were initially excluded from protection for a presumed lack of industrial applicability.

[58] See *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 21.

[59] See M. FISHER, *Second Medical Indications and the Swiss-Form Claim: Taming Frankestein's Monster: Part 1 – Solving One Problem Creates Another*, in 2017 *E.I.P.R.*, 39, 574, at 578-597 highlighting how the EBOA purposefully disregarded the intention of the EPC 1973 signatories, which was clearly against the extention of patent protection to further medical use inventions.

[60] See J. COCKBAIN, S. STERCKX, *Purpose-limited pharmaceutical Product Claims under the Revised European Patent Convention*, (nt. 26), at 90, observing the departure from previous case law of the Board which generally does not allow novelty of the invention to be assessed from the intended purpose of the end product, but rather from its technical features. Similarly see B. DOMEIJ, (nt. 10), at 131. See also J. COCKBAIN, S. STERCKX, *Is the Enlarged Board of Appeal of the European Patent Office Authorised to Extend the Bounds of the Patentable? The G-3/85 Second Medical Indication/ESAI and G-2/08 Dosage Regime/ABBOTT RESPIRATORY Cases*, in 42 *I.I.C.*, 257, 2011, at 265.

inventions [61] and, consequently, their infringement [62]. The EBoA, indeed, precisely decided not to follow the lead offered by the German approach to the matter at the time, which anchored protection of second medical use invention to the element of *augenfällige Herrichtung* (i.e. manifest arrangement) [63], leaving matter of infringement to National Courts [64].

Lacking any clear indication from the EPO in this regard, scope of protection for Swiss-type of claim invention remained vague at best. It was not clear, in particular, whether protection in such a case would extend or not to the products directly obtained throughout the claimed manufacturing process, as generally envisaged by art. 64, 2°, EPC 2000 for process inventions [65]. While

---

[61] See at this regard E. VENTOSE, *Medical Patent Law – The Challenges of Medical Treament*, Cheltenham UK-Northampton, MA, USA, Edward Elgar Publishing, 2011, at 238, arguing that if both the (manufacturing) process and the derived products are known to the state of the art and the patent merely teaches how to use the invention in the medical field, then the invention only evolves around a new use claim, which could just amount to an excluded method of medical treatment.

[62] This is precisely the reason for which the EBOA in *ABBOTT Respiratory* will eventually abolish this claiming format (i.e. for "[…] the absence of any functional relatioship of the features (belonging to therapy) conferring novelty and inventiveness, if any, and the claimed manufacturing process". See *ABBOTT RESPIRATORY/Dosage Regime*, G 2/08, 19 February 2010, [2010] E.P.O.R. 262, § 7.1.3, *infra* § 6.

[63] The EPO Enlarged Board of Appeal was familiar with German approach to second medical use inventions widespread at that time, as confirmed in the *Hydropyridine* decision (Decision X ZB 4/83), asking for the invention to result in the manufacturing of a product whose appereance – i.e. its external packaging or the information contained in the information leaflet thereby contained – clearly bore a manifest link to the therapeutical use for which protection had been sought. However, the EBoA explicitly explained that it could not embrace the approach promoted by one jurisdiction only, no matter how authoritative it was. See *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 17-18.

[64] The EBOA declared indeed that matters of infringement, pursuant to art. 64, 3° EPC had to be left to National courts. See *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 18. Such short-sighted approach, heavily criticized by M. Fisher, has been later corrected by the amendments introduced by the EPC 2000. M. FISHER, (nt. 59), at 597.

[65] While art. 64 EPC does not enter into details with regard to the exclusive rights conferred by the patent, referring to the national patent laws of the States where protection will be validated, art. 64, 2° EPC demands that if the subject-matter of the European patent is a process, the protection conferred by the patent shall extend to the products directly obtained by such process. The framers did not want eventually to accept the proposal of the Swiss delegation to introduce a rebuttable presumption of infringement in favour of the patentee when the products directly obtained through the patented process were new. See M.S. SPOLIDORO, *Revisione della legislazione nazionale in materia di brevetti per invenzioni industriali, commento all'art. 2 D.R. n. 1127 del 1939*, in *Nuove leggi civ. comm.*, 1981, 678, at 683. Such a mechanism will be later introduced by the TRIPs Agreement (art. 34). See *infra* note 68.

this construction would seem logical at first sight and in line with the fact that novelty of second (medical) use invention must to be searched for in the new therapeutical application of the known substance (i.e. the medicament), it is worth recalling that such protection is justified and therefore accorded when the products are made through a *new* and *inventive process*. In other words, it is the patentability of the process in itself that matters: should the process be patentable and should such process happen to be one dealing with manufacturing or anyhow with the making of final products, then in order to better protect the process [66], protection is further extended to the products directly obtained, regardless of whether they can autonomously be patented or not [67]. This clearly emerges from the circumstance that the provision does not condition its protection to the circumstance that the product be new [68] or inventive, as in such a case the inventor could easily get a product patent [69], but rather to the

[66] In this sense see G. DRAGOTTI, *Brevetti di prodotto, di procedimento e invenzioni d'uso dopo i Gatt-TRIPs*, in *Riv. dir. ind*., 1997, I, 99, at 105. A. VANZETTI, V. DI CATALDO, (nt. 27), 444 and ff.

[67] In this way, G. FLORIDIA, *Procedimento e prodotto nelle invenzioni farmaceutiche*, (nt. 16), at 49-50. G. SENA, (nt. 12), at 320.

[68] Thanks to the harmonization following the signing of the TRIPs Agreement, many national patent laws today envisage a *prima facie* presumption of infringement applying when the directly obtained products happen to be new. In such a case, identical products released on the market by a third un-authorized party will be deemed infringing, unless the latter is capable of proving that he manufactured them through a different process. It has been rightfully pointed out, however, that such a rule has only procedural value, reversing the burden of proof when no similar products existed in the market before the ones directly obtained through the new patented process. It seems, therefore, that novelty in this case cannot be given the same contours it has pursuant to Art. 54, 1°-3°, EPC. See G. FLORIDIA, *Procedimento e prodotto nelle invenzioni farmaceutiche*, (nt. 16), at 51; *contra* G. GUGLIELMETTI, *Commento al d.lgs. 19 marzo 1996, n. 198, sub art. 13 Legge Invenzioni*, in *Nuove leggi civ. comm.*, 1998, 118, at 121.

[69] If product protection represents a feasible option for the patentee, he will surely choose to follow such path, as such protection is the strongest, covering against all identical products entering the market, no matter how they have been produced. In this sense: A. VANZETTI, *Procedimento, prodotto e unicità dell'invenzione*, in *Studi in memoria di P. A.E. Frassi*, Milan, Giuffrè, 2010, 755. Claiming both process and product protection, however, might be convenient for the patentee whenever the former has some impact on some specific features of the latter or where the latter (take, for example, a chemical substance) is already available in other forms but it can be produced in a purer or more advanced form thanks to the process. In all these cases, normally addressed to as *product-by-process* inventions, the patentee will find valuable to claim within the same patent the product as obtained through a certain the specific process. See V. DI CATALDO, *La brevettabilità delle biotecnologie. Novità, attività inventiva, industrialità*, in *Riv. dir. ind.*, 1999, I, 177, at 180-184; ID., Note, however, that *product-by-process* inventions seem to receive different protection from the one insisting on products directly obtained

sole circumstance that the items be *directly obtained* through the claimed process [70]. And indeed it is commonly accepted that (even identical) products made through a different method or process (than the patented one) will not be infringing [71].

In conclusion, it seems that while this form of protection can be surely helpful to protect some subject matters belonging to the pharmaceutical sector, such as for product-by-process inventions typical of the biotechnological sector [72], its applicability to Swiss-type of claims remained uncertain.

5. *The expansionist trend of second medical use inventions. What does "further" use expressly mean?*

The term second use patent in the medical field has been initially intended, at least by scholars, as referring to an invention consisting in a second mode of employment of a known product, patented in light of a first medical use, in a way to treat [73] a *different* ailment than the one targeted by the first patent [74].

---

through a process invention, as in the latter case the invention would always be a process invention, *product-by-process* inventions seem to be equated to product inventions. ID., *Biotecnologie e diritto. Verso un nuovo diritto, e verso un nuovo diritto dei brevetti*, in *Contr. impr.*, I, 2003, 319, at 378 and ff. In the same way: M. SCUFFI, *Product-by-process claims: un contrastato impiego nell'invenzione chimico-farmaceutica e biotecnologica*, in *Dir. ind.*, 2002, 340, at 344.

[70] This requirement has been interpreted strictly, in a way to exclude protection every time there are intermediate production steps to finalize the product and the items are not the direct and tecnhnically inevitable result of the patented production process. At this regard see A. VANZETTI, V. DI CATALDO, (nt. 27), 445. L. BENTLEY, B. SHERMAN, D. GANGJEE, P. JOHNSON, *Intellectual Property Law*[5], Oxford, Oxford University Press, 2018, at 648 and ff.

[71] See G. FLORIDIA, *Le creazioni intellettuali a contenuto tecnologico*, in *Diritto Industriale, Proprietà Intellettuale e Concorrenza*[6], Turin, Giappichelli, 2020, at 251. This circumstance explaning why product protection, being absolute, is always preferrable to process protection for the inventor. And indeed, in case of a product patent, an identical product manufactured through a different process would be deemed infringing. See V. FALCE, (nt. 3), at 246.

[72] In this sense: A. MUSSO, (nt. 13), at 190 and ff.

[73] It is important to point out that the decision of the EBOA in *EISAI* was rendered in relation to second or further *therapeutic* applications of a known substance. Nonetheless, it is appropriate to interpret the principle stated therein broadly in a way to encompass also new uses of substances manufactured to be implemented in a diagnostic or surgical method. Extensively on the point see E. VENTOSE, *Medical Patent Law*, (nt. 61), at 256 and ff.

[74] See F. BENUSSI, (nt. 26), at 105; D.R. SCHNEIDER, (nt. 26), at 521, explaining that the critical limit was reached when further second use inventions were patented for the treament of

This case, indeed, was surely the most straightforward to address, given that the novelty of the invention – deriving from the new and specifically claimed use – would lay in the possibility of treating an illness not previously treated by means of the known substance as patented: hence, the invention solved a new technical problem [75]. In the aftermath of *EISAI*, however, the jurisprudence of the Technical Boards implemented the new *Swiss type of claim* format to second medical use invention very broadly, stretching the boundaries of patentable subject matter way beyond the requirement of a new different disease to be treated.

a) *Transposition of the therapeutical effects on a new class of patients.*

In *DUPHAR/Pigs II* the Board granted protection, in the form of a second medical use invention, to the therapeutical application of a vaccine, which was already known to be effective in the treatment of a certain class of animal (i.e. sero-negative pigs), with regard to a new and different class of animals (i.e. sero-positive pigs) [76]. The Board clearly recognized that, different from the circumstances in *EISAI*, the alleged second medical indication in this case was not aimed at curing a different ailment. The question, therefore, concerned whether the newly discovered efficacy of a vaccine (to immunize against a known illness but) in relation to a *different class* of animals (than the ones it had already been proven useful for) could be considered a new therapeutic application, from which novelty could be inferred in accordance with the principles of the Enlarged Board's Decision [77]. The question was positively answered by the Board, explaining that "[…] a new use is not only valuable in cases where a novel area of therapeutic use, i.e. a novel medical indication, is provided but also in those cases where a novel class of animals, *which previously did not respond to a medicament*, is cured or protected against a disease (ital-

---

the same illness with the same compound. B. DOMEIJ, (nt. 10), at 130. E. VENTOSE, *Medical Patent Law*, (nt. 61), at 240; H.-R. JAENICHEN, J, MEIER, N. HOLDER, *Medical Use Claims: EPC2000 and its Impact on Prosecution and Enforcement*, in *Patent and Technological Progress in a Globalized World*, (nt. 24), 255, at 256.

[75] In this way: E.D. VENTOSE, *Patent Protection*, (nt. 27), at 67.

[76] See *DUPHAR/PigsII*, case T 19/86, 1988, 1 E.P.O.R. 10. The technical problem underlying the present invention was, indie, intended as the provision a method of immunization applicable to sero-positive piglets against Aujeszky's disease. The Technical Boards adopted similar views in *Controlling bleeding/QUEEN'S UNIVERSITY KINGSTON*, T 893/90, of 22 July 1993, r.d. § 4.3., concerning bleeding control in non-haemophilic mammals (as specific classo of patient with different features than haemophilic mammals.

[77] *DUPHAR/PigsII*, case T 19/86, 1988, 1 E.P.O.R. 10, r.d. § 6.

ics added)"[78], and therefore concluding that "[…] the question whether a new therapeutic use is in accordance with the decision GR 05/83 should not be answered exclusively on the basis of the ailment to be cured but also on the basis of the subject (in the present case the new group of pigs) to be treated"[79].

b) *Different way of functioning of the medicament at a physiological or at a cellular level.*

Another peculiar case concerned circumstances where the further medical application was recognized in the different way of functioning of the medicament at a physiological or at a cellular level[80]. In *ICI/Cleaning Plaque*, for example, the invention under scrutiny regarded a treatment of the human body with the same active substance (i.e. lanthanum salts), for the same therapeutic purpose (i.e. prevention of tooth decay), of a previously granted (and expired) patent[81]. The Board considered that while the therapeutic purpose could seem the same, the prior art document disclosed the use of lanthanum salts in dental compositions for the purpose of depressing the solubility of tooth enamel in organic acids, thus strengthening the enamel so as to inhibit tooth decay. Quite differently, the claimed invention was aimed at improving the removal of plaque from teeth by using compositions including lanthanum salts in a way to inhibit tooth decay, which would be caused by the presence of the plaque. Thus, according to the Board the claimed invention brought up a novel and different technical effect which represented a further novel therapeutical application pursuant to *EISAI*[82].

c) *Alteration of the original form of administration.*

From there, the expansionist trend of the Technical Boards went on to broaden patentable subject matter in a way to further extend protection to inventions amounting to an alteration of the original form of administration of a

[78] The requirement of the *different* class has been later specified to be intended as "[…] a new group of subjects which is distinguished from the former by its physiological or pathological status". See *Adrenaline/MEDCO RESEARCH*, T 233/96, 4 May 2000, unreported, r.d. § 8.7., where the Technical Board further stated that the choise of the new group of patient must not be arbitrary, which means that "[…] there must exist a *functional relationship* between the particular physiological or pathological status of this new group and the therapeutic effect obtained".

[79] *Id.*, § 8.

[80] In this sense see D.R. SCHNEIDER, (nt. 26), at 522.

[81] See *ICI/Cleaning Plaque*, case T 290/86, 11 November 1990, 1991 E.P.O.R. 157.

[82] *Id.*, r.d. § 6.1.

certain pharmaceutical substance [83]. In *HCG/SERONO* the invention regarded the use of human chorionic gonadotrophin (HCG) for the manufacture of a medicament aimed at treating male sexual disorders [84]. The invention was once again claimed pursuant to the Swiss type format, the alleged novelty and inventiveness of the technical contribution lying in the subcutaneous form of administration. Protection had been initially denied in light of a prior art document showing the use of the same substance to treat the same ailment via intramuscular injection. By contrast, on appeal The Board acknowledged that the question to be decided regarded precisely "whether a difference in the mode of administration of a medicament can be treated as a new therapeutic use" [85] and took the view that "mode of administration may be a critical factor in a medical treatment, and no reason can be seen for any a priori bar to relying on this difference when distinguishing over the prior art. Rather patentability must be treated as depending only on whether this modification is in fact novel and inventive" [86]. In a similar fashion, in *Trigonelline/MAI* the Technical Board granted protection to a second medical use invention consisting in the use of trigonelline (substance extracted from fenugreek seeds) for the production of capsules (for peroral administration) for reviving, stimulating and enhancing hair growth in living creatures, whereas the prior art contained plenty of anticipating documents, in particular one disclosing the use of fenugreek seeds in a compound (containing ten plant substances) administered in topical form (i.e. as a lotion to be put on the sculp) to treat hair loss and stimulate hair growth [87].

---

[83] Those possibilities had been expressly envisaged indeed in *Second medical indication/EISAI*, G 5/83, 1985 O.J. EPO, r.d. § 20, where the Technical Board said "where the medicament itself is novel in the sense of having novel technical features – e.g. a new formulation, dosage or synergistic combination – the ordinary requirements of Article 54(1) to (4) EPC will be met […]".

[84] See *SERONO/Subcutaneous administration of human chorionic gonadotrophin*, case T 51/93, unreported, 8 June 1994.

[85] See *SERONO/Subcutaneous administration of human chorionic gonadotrophin*, case T 51/93, unreported, 8 June 1994, r.d. § 3.1.1.

[86] See *SERONO/Subcutaneous administration of human chorionic gonadotrophin*, case T 51/93, unreported, 8 June 1994, r.d. § 3.1.2.

[87] See *Trigonelline/MAI*, case T 143/94, of 6 October 1995, in O.J. EPO 1996, 430, r.d. § 7.2. and ff. According to the Board, "[…] document (43) […] describes a topical preparation for the treatment of hair growth problems, [whereas] the problem addressed by the contested patent can be viewed in providing an alternative mode of administering such a preparation using trigonelline, or more specifically fenugreek seed". *Id.* r.d. § 8.1.

d) *Different dosage regimen: the last bastion to conquer.*

A very controversial case within the patentability of second medical use invention has regarded the case of new dosage regimens. The early approach of the EPO Chambers in this instance seemed to be very much influenced by the German jurisprudence where the Supreme Court denied protection on the ground that administration regimen constituted an abstract medical activity, therefore not patentable pursuant to the equivalent German provision of art. 52(4) EPC 1973 [88].

In *PROCTER & GAMBLE/Gastrointestinal compositions*, the Board denied protection to an invention consisting in the use of a combination of two known substances for the manufacture of a known medicament for treating or preventing gastrointestinal disorders, where the only distinguishing technical feature amounted to the slightly different prescribed regimen for the treatment [89]. While the ultimate decision of the issue was greatly facilitated by the presence of anticipating prior art [90], the Board took great care in explaining that "[…] determination of the best individual treatment schedule, in particular the prescribing and modification of drug regimens used for administering a particular medicament, so as to comply with the specific needs of a patient, appear to be in the first place part of the typical activities and duties of the doctor in attendance in exercising his professional skills of curing, preventing or alleviating the symptoms of suffering and illness. These are, however, typical non-commercial and non-industrial medical activities which Article 52(4) EPC 1973 intends to free from restraint" [91].

Similar conclusions were achieved in *Thiazide diuretics/EURO-CELTIQUE*, regarding the administration of a known medicament (i.e. thiazide diuretics) in a particular prescribed dosage regimen for the (known) treatment of hypertension (without simultaneously causing effective diuresis) [92]. Here once

[88] See German Federal Supreme Court decision of 19 December 2006 – *Carvedilol II*, 38 *IIC* 481. Significantly, the Court stated that administering a medicament and determining a suitable therapy plan for a patient are characteristic part of the activities of the treating physician, hence excluded from protection under Art. 52(4) EPC 1973.

[89] See *PROCTER & GAMBLE/Gastrointestinal compositions*, case T 0317/95, 26 February 1999, unreported.

[90] See *PROCTER & GAMBLE/Gastrointestinal compositions*, case T 0317/95, 26 February 1999, unreported, r.d. § 4.4, noting that even the class of patients was identical and that there was evidence showing that the administration of the two substances in combination had already been pursued by a hospital physician.

[91] *Id.*, r.d. § 4.5.

[92] *Thiazide diuretics/EURO-CELTIQUE*, T 0056/97, 30 August 2001, unreported.

again the Board expressed the view that protection could not be granted when novelty exclusively hinged upon activities which were non-commercial and non-industrial: i.e. medical activities, which the EPC framers intended to remain free and unconstrained [93].

While this view was defended for a while by the Technical Boards in several other decisions [94], it didn't take long for the reasons and needs of the pharmaceutical industries to break this wall and convince the EPO of their soundness. In *GENENTECH/Method of Administration of IGF-I* [95] the Board argued that it did not see any reason to set an *a priori* ban against the protection of the efforts of a person who develops a novel therapy by looking for the most effective way in which a known composition can be administered, denying "even the limited form of patent protection of second medical use […] without an examination of whether the therapy is indeed novel and inventive" [96].

The *GENENTECH* decision marks a milestone within the case law of the EPO Technical Boards, as not only the Board openly discarded previous decisions standing against the patentability of dosage regimens [97], but it also paved the way to eventually set aside the discussion on whether novelty of second

[93] See *Thiazide diuretics/EURO-CELTIQUE*, T 0056/97, 30 August 2001, unreported, § 2.5, defining the claimed invention "an unsuccesful attempt to obtain protection for a method of therapeutic treatment of the human or animal body by couching it in the form of a Swiss type claim".

[94] Similar conclusions were reached in *Use of Nicotine/ELAN CORPORATION*, case T 0584/97, 5 December 2001, unreported, denying protection (for lack of novelty) to an invention claiming the use of a substance (nicotine) for the manufacture of a medicament (a kit containing sub-therapeutic and therapeutic units) for therapeutic application (the treatment involving conditions susceptible to nicotine therapy involving the separate or sequential administration of increasing doses of nicotine. See also *Liposome composition/SEQUUS*, case T 04/98, 9 August 2001, [2002] E.P.O.R. 371, r.d. § 8, where the Board held that the "three times dosage" added at the end of some of the claims, as the sole and only distinguishing technical feature, was not enough to infer novelty.

[95] *GENENTECH/Method of Administration of IGF-I*, case T 1020/03 2006 E.P.O.R. 67. The case involved the use of a known substance (i.e. insuline-like growth factor-I) in the preparation of a known medicament to treat chronic renal failure in mammals according to a very specific administration pattern (specifically alterning administration cycles with periods of discontinuation and repetition of such alternation of cycles for as long as necessary to maintain the renal function of the mammal active).

[96] *Id.*, § 43. The Board further argued that while it is the physician's duty to treat his patients applying the best method of treatment known, knowledge regarding efficacy and effectiveness of different treatments is gained through experiments and testing, which need to be financed. *Id.*, § 46.

[97] *Id.*, § 40.

medical use inventions had to be interpreted as requiring a different ailment to be treated. With specific regard to the latter issue, the Technical Chamber in *GENENTECH* openly rejected any reading of *EISAI* which would hint to such a direction arguing that, while it was surely easier to positively assess novelty in a second use claim when the invention was aimed at solving a different technical problem (i.e. the different disease), nothing in the text of the decision excluded protection of different types of second use inventions [98]. Moreover, the Board warned against adopting such a narrow construction of the novelty requirement which would have constrained the examiner to restrict his analysis to the compositions claimed and the illnesses to be treated, ignoring any other potential innovative features of the method set out in the claim [99]: such an approach, argued the TBA, would carry negative effects not simply to the interests of the pharmaceutical industry, but for the innovation process at large, slowinging down the knowledge on how medicines can be most effectively used [100].

6. *The amendments of the EPC 2000 and the new frontiers of second use patents.*

Given the increased importance of second use inventions in the medical field [101], when times were ripe for a revision, EPC signatory Countries decided to put to rest once for all the praetorian law [102] created by the EBoA in *EISAI*

[98] *Id.*, § 72.

[99] *Id.*, § 74.

[100] *Id.*, § 75. The incentive *rationale* and the needs to protect the economic interests of the pharmaceutical industry, even if to the ultimate benefit of society at large, is persistent throughout the decision. See also § 46 (last part) where the Board expressly states that "Allowing second medical use patents serve sto increase the possibilities of someone undertaking the necessary research. If the possibility of obtaining a financial return is excluded less research is likely to take place".

[101] This in particular is due to the explosion of so called "personalized medicine", whereby molecular profiling is used for the tailoring of the right therapy for the right person. The development of personalized medicine, in turn, will lead into so called "stratified medicine" whereby doctors will be able to group patients with a similar molecular profile and target specific treatments to different patients subgroups. The spreading of personalized medicine is likely to spur the recourse to second (and further) medical use inventions. See S.J.R. BOSTYN, *Personalised medicine, medical indication patents and patent infringement: emergency treatment required*, IPQ, 2016, 151, at 153 and ff.

[102] Such words have been used by the very same EBoA in *ABBOTT RESPIRATORY/Dosage Regime*, G 2/08, 19 February 2010, [2010] E.P.O.R. 262.

by introducing clear-cut amendments to the Convention, which would eliminate any legal uncertainties regarding the patentability of further medical uses [103]. With specific regard to second medical use inventions in particular Art. 54 was substantively amended so that its new version, contained in the so called EPC 2000, embedded a new 5th prong (the existing one becoming the 4Th of the same article) specifically meant to extend patent protection to any further medical use of a known substance or composition (already patented in light of a first medical application). In the wording of the new prong, patent protection will not be excluded for any known substance or composition for "[…] *any specific use* in a method referred to in Article 53(c) EPC 2000, provided that *such use* is not comprised in the state of the art" [104].

While the aim of such amendment was claimed to be the granting of a form protection equivalent to that offered by Swiss-type of claims [105], in a way to set aside such claiming format and bring clarity and certainty in the field, it seems none of such goals were achieved. It is worth pointing out that the enactment of the EPC 2000, which happened to enter into force only in 2007, did not mark the end of Swiss-type of claims. In lack of an express elimination of the latter, the EPO divisions keeped releasing titles of protection drafted in such claiming format until the EBoA in *ABBOTT RESPIRATORY/Dosage Regime* sanctioned its express abolition in 2010 (to be effective in early 2011) [106].

---

[103] Quite critical in this regard is Fisher who eloquently describes the amendment to the EPC as "[…] as ex-post legislative tidying of the mess created by the Enlarged Board in *EISAI.* See M. FISHER, (nt. 59), at 579.

[104] Note the clear difference in language with the previous prong, now Art. 54(4) EPC 2000, stating that protection is not excluded for "[…] any substance or composition, comprised in the state of the art, *for use* in a method referred to in Article 53(c), provided that *its use for any such method* is not comprised in the state of the art (italics added)", where the generic mention to "use" and the linking of the novelty requirement to the circumstance that the use for "any such method" is new were aimed at circumscribing protection to the sole istance of the first medical use conceived of a substances previously known for its mode of employment in different sectors.

[105] See at this regard the wording of the Swiss Delegation at the Revision Conference where it stated that the new art. 54, 5°, EPC, "[…] unambiguously permits purpose – related product protection for each further new medical use of a substance or composition already known as a medicine" and that "This protection is equivalent, as far as the further uses are concerned, to that offered by the 'Swiss type claim'. In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a 'Swiss type claim'". The explanatory notes drawn up by the Swiss Delegation, MR/l8/00, point 4, Munich, November 21st 2000.

[106] *ABBOTT RESPIRATORY/Dosage Regime*, G 2/08, 19 February 2010, [2010] E.P.O.R.

This means that up to 2031 at least (as the grant of a CPC could prolong duration of other five years) Swiss-type of claim inventions will coexist with the new purpose-bound product protection format introduced by the EPC 2000, which renders clarification on any like difference in scope of protection even more compelling.

6.1. *The meaning of "any specific use" within the context of novelty of the invention and the patentability of new dosage regimens.*

The perimeter of the new Art. 54(5) EPC 2000 was deeply explored by the Enlarged Board of Appeal following the remittal by the Technical Board in *KOS LIFE SCIENCES INC/Dosage regimen* [107]. The invention claimed the use of nicotinic acid for the manufacture of a sustained release medicament for use in the treatment of hyperlipidaemia by oral administration. Whereas the use of nicotinic acid in the treatment of hyperlipidemiae was known at the time of filing, as shown by prior art documents, the patentee argued that (second medical use invention's) novelty stemmed from claim 1 expressly indicating a different dosage regimen (i.e. "once per day prior to sleep"). The Examining division, however, refused protection on the basis that the specific drug administration regimen constituted a medical activity excluded from patentability (by Art. 52(4) EPC 1973) and therefore could not be considered a further medical indication from which novelty could be inferred [108]. Confronted with the issue, the Board of Appeal deemed that the points of law at issue deserved clarity and remitted the case before the EBoA precisely asking whether, from a joint reading of new Art. 53(c) and Art. 54(5) EPC 2000, protection could be granted to a second use of the medicament providing a new and inventive treatment by therapy of a certain illness when the very same medicament was already known to be useful for that specific illness. Secondly, assuming a positive answer to the first question, the Technical Board asked whether patenta-

262, r.d. § 7.1.2.-7.1.4. Following the decision the EPO issued a formal notice (*Notice from the European Patent Office dated 20 September 2010 concerning the non-acceptance of Swiss-type claims for second or further medical use following decision G 2/08 of the Enlarged Board of Appeal*, O.J. EPO 2010, 514) to clarify that Swiss-type of claim format could not be anymore acceptable after 28th January 2011 (three months later the official publication of the decision, as decided by the EBoA).

[107] *KOS LIFE SCIENCES INC/Dosage regimen*, case T1319/04, 22 April 2008, unpublished.

[108] *Id.* r.d. §§ 27-28.

bility could be possible even in istances where the only novel feature of the treatment was a new and inventive dosage regime [109].

The EBoA started its analysis by examining at length the new EPC provisions, as modified by the EPC 2000 [110], especially concentrating on the new prong of Article 54 EPC introducing protection for further medical use inventions. Following the same line of reasoning of the TBA in *GENETECH* [111], the EBoA asserted that Article 54(5) EPC did not define any degree of distinctiveness the new use must possess in order to qualify for protection [112], and that limiting patentability of further medical use inventions only to cases of inventions aimed at treating a different illness than the one targeted by a previous patent (regardless whether first or second use patent) would amount to an arbitrary reading of the provision, at odds with the good faith principle stated in Article 31(1) of the Vienna Convention [113].

With regard to the specific subset of cases represented by further medical use inventions whose only distinguishing feature lays in a different dosage regimen, the EBoA stated that it did not see any good reasons in principle to treat this type of inventions *a priori* differently from any other further medical use inventions. Although in theory new dosage patents could be seen as a vehicle to unduly prolong patent protection, the EBoA was confident that such a risk will be eluded thanks to the inventive step hurdle, which will further demand that the claimed dosage regimen be not simply verbally different from the prior art, but also reflecting a different (and inventive) technical teaching [114].

---

[109] See *ABBOTT RESPIRATORY/Dosage Regime*, G 2/08, 19 February 2010, [2010] E.P.O.R. 262, Summary of Facts, § I.1.

[110] And indeed, as the patent application was still pending in December 2007, the Board decided that – pursuant to the Decision of the Administrative Council of 28 June 2001 on the transitional provision under art. 7 of the Act revising the European Patent Convention of 29 November 2000, Article 1, No. 1 and 3 – the case had to be decided in light of the new provisions contained in the EPC 2000.

[111] In *GENETECH*, the Technical Board explained that the words "any specific use" within the new Art. 54(5) (not entered into force at the time of the decision) would not demand a further hurdle, within the novelty assessment, to comply with for further medical uses to be patentable: namely that the new therapy be specified in some very extensive and detailed way, so as to show its intrinsic novelty. *GENENTECH/Method of Administration of IGF-I*, case T 1020/03 2006 E.P.O.R. 67, § 51.

[112] *ABBOTT RESPIRATORY/Dosage Regime*, G 2/08, 19 February 2010, [2010] E.P.O.R. 262, r.d. § 5.9.1.

[113] Vienna Convention on the Law of Treaties concluded on 23 May 1969 (hereinafter "Vienna Convention"). See *Id.*, § 5.9.9.1.

[114] *Id.*, § 6.3., second indent.

6.2. *The meaning of "any specific use" and the scope of protection of further medical use inventions.*

So what is the purpose of the introduction of the wording "any specific use" as opposed to the more generic "for use" (in a method referred to in Article 53(c) [115]) of the fourth prong of Art. 54 EPC? There is widespread consensus that such wording is meant to grant limited protection to the product claimed in the invention (i.e. the substance or composition), whose scope is therefore limited to the specific function or purpose of the product, as specified in the patent, in the "for the use in the treatment of …" part of the claim [116]. This interpretation, which is in line with the intentions of the framers of the Revision, has been embraced also by the EPO Chambers that have agreed on the circumstance that the only appropriate way to interpret the wording "any specific use" within such provision is to refer it to the scope of protection, which is limited to the specific claimed use, as opposed "[…] to the generic broad protection conferred by the first claimed medical application of a substance of composition, which is in principle not confined to a particular indication" [117]. And indeed, while the latter could just vaguely claim some sort of medical use, being the substance known for its previous application in a different (non-medical) sector, second medical use inventions must demonstrate their departure from the first-use invention, hence they needed to claim a *specific* use within a method referred to in Article 53(c) EPC2000 [118].

Pursuant to the jurisprudence of the EPO Technical boards there would seem to be a hierarchy, therefore, in patent breadth – hence, strength – in the medical field, where (structurally) new compound or substances patented for the first time for a medical application would receive the strongest protection [119]: what we could call "absolute and across-sectors" product protection.

---

[114] In *Hoffman La Roche/Pyrrolidine derivatives*, T 128/82, *supra*, r.d. § 11, the Technical Board clarified that the word "a" of Article 54, 5°, EPC 1973 (today 54, 4°, EPC 2000) should not be interpreted as having a numerical significance, and therefore the scope of protection should not be limited to the one therapeutical method first brought into light with the first medical patent.

[116] See, more extensively, S.V.R. BOSTYN, *Patenting DNA Sequences*, (nt. 20), at 56-60; D.R. SCHNEIDER, (nt. 26), at 517; H. AHN, (nt. 3), at 51.

[117] *ABBOTT RESPIRATORY/Dosage Regime*, G 2/08, 19 February 2010, [2010] E.P.O.R. 262, r.d. § 5.10.3.

[118] *GENENTECH/Method of Administration of IGF-I*, case T 1020/03 2006 E.P.O.R. 67, r.d. §§ 48-52.

[119] See *supra* the authors quoted in note 20.

Second in rank, there would be first medical use inventions. In this case, indeed, according to the EPO jurisprudence, protection would extend to all unforeseen *medical* uses of the compound and would not be anyhow limited in scope to the first therapeutical method of employment as described in the patent [120]. In this latter case, therefore, it would be more appropriate to talk about "sector-bound" product protection (or "absolute purpose-bound" protection). Eventually, subsequent medical uses of such compounds or substances would receive "purpose-restricted product protection" [121], meaning that inventors would be entitled to use the known compound or substance only with regard to the specific highlighted medical use [122].

Within this framework, which is not devoid of criticisms, one should decide where to put second medical use inventions claimed pursuant to a Swiss-type of claim format, since we have seen that this type of patents will be around for quite some time still. It is not clear, in particular, whether such inventions would receive the same protection of second medical use inventions claimed pursuant to new Art. 54, 5° EPC 2000, hence to be placed in the same level of the afore depicted pyramid, or if, on the contrary, their protection would be somewhat more restricted, in a way to constitute the fourth – and the lowest – level of protection in terms of patent scope. It is still controversial, indeed, whether the change in the novelty provision has broadened or not the quantum of protection granted to second medical uses by the EISAI decision [123].

While it is obvious that EPC framers wanted to eliminate Swiss-type of claim inventions, whose construction proved to be way too cumbersome, it is not as clear if they intended the new type of inventions to exactly match the scope of protection of – hence, replace – the preceding one. A mere look at the literal wording of new the provision would surely militate for a strengthening of protection. And indeed the new indent of art. 54(5) EPC 2000 talks about

---

[120] see also D.R. SCHNEIDER, (nt. 26), at 517 and 521. In particular, Schneider argues that second use inventions would differ from first use inventions in that only in the former case the "specific use" must be included in the claim, whereas in first use invention the use – despite it needs to be specific and substantial – can be simply disclosed.

[121] See *Board of Regents, The University of Texas System/Cancer Treatment*, T 1780/12, unpublished, r.d. § 3-4.

[122] See B. DOMEIJ, (nt. 10), at 133. *Contra* see R. MOUFANG, *Patentability of pharmaceutical innovations*, (nt. 35), 54, at 57 and 67. According to Moufang both first and further medical indications of known substances or compositions should be afforded use-limited product protection.

[123] Sir Robin Jacob has recently asserted that patents on second medical uses are "patents of uncertain scope". See J. NURTON, (nt. 49), 1.

protection of "compositions" or "substances", which clearly implies a shift from process protection, as intended in *EISAI*, to product protection. As a consequence, despite being both limited to the specific use claimed, it would seem logical to assume that protection offered by purpose-limited product invention be broader in scope than the one offered by a manufacturing process claiming the use of a certain substance for the manufacturing of a medicament to be used for a certain claimed use. It seems that this latter idea has been also followed by the EPO Chambers in the *Board of Regents* decision where the Board explicitly made clear that purpose-limited product claims and purpose-limited process claims belong to different claim categories and that therefore the latter confers less stringent protection [124]. The Technical Board, however, went one step ahead in this decision and in the attempt to clarify things, only made the situation worse. With regard to second medical use claimed pursuant to a Swiss-type of claim format, the Board eventually clarified that Art. 64(2) EPC applied because the claim was towards a manufacturing process and protection would therefore extend to the products directly obtained. Furthermore, the Board added that "[…] the product directly obtained is the *manufactured medicament* which contains as an active substance human alfa glucosidase in the 100 to 110 kd form and which is *packaged and/or provided with instructions for use* in the treatment of infantile Pompe's disease" (Italics added) [125].

The clarity of the above paragraph, however, was followed by a quite unclear description of the scope of protection of second medical use inventions claimed as purpose-bound product inventions. At this latter regard, indeed, the Board stated that the invention "[…] drafted as a purpose-limited product claim […] confers protection [on the human acid alpha glucosidase in the 100 to 110 kD form,] *whenever it is being used for the treatment* of infantile Pompe's disease." Adding that "since the claim does not refer to a step of manufacture of a medicament, the product claimed, i.e. the human acid alpha glucosidase in the 100 to 110 kD form, *is not limited to a manufactured medica-*

[124] Cfr. *Board of Regents, The University of Texas System/Cancer Treatment*, T 1780/12, 30th January 2014, ECLI:EP:BA:2014:T178012.20140130, r.d. § 22. The case specifically addressed the question of whether an amendment concerning only a change in the format of a claim from a Swiss-type use claim to a purpose-limited product claim, as introduced by new Art. 54(5) EPC 2000 would have the effect of broadening the scope of protection and was therefore not allowable pursuant to Art. 123(3) EPC (expressly sanctioning that patent applications cannot be amended "in such a way as to extend the protection it confers").

[125] *Id.*, § 9.1.

ment, packaged and or/with instructions for use in the treatment of infantile Pompe's disease (emphasis added)" [126].

Such broad construction of the (second use) invention when claimed as purpose-limited product invention was surely intended at marking the difference with the previous claiming format and, in particular, to stress that the former (being for product inventions rather than process) confers broader protection [127]. It seems, however, that the proposed scope of protection (for whatever use or method of employment of the claimed compound in the treatment of the identified pathology) risks being overly broad. And infact, at a closer look, the purpose-limited product claim was directed at the substance (the human acid alpha glucosidase in the 100 to 110 kD form) for use in the treatment of a specific ailment (i.e. infantile Pompe's disease) "wherein the human acid alpha glucosidase is to be administered intravenously, and wherein the treatment is to be continued for at least 4 weeks" [128]. It is not clear while the Board proposed such a broad claim construction, not taking into account the specific limitation of use provided for by the very same patentee.

In the last part of the decision, the Board attempted to timidly address (without calling things with their own names) the issue of infringement arising whenever two different medicinal products, protected through different second therapeutical use patents, happen to be identical in composition and pharmaceutical form and can be used interchangeably for one of the patented use [129]: a

---

[126] *Id.*, § 9.2.

[127] As it is in fact confirmed by the Board, clarifying that even if, thanks to Art. 64(2) EPC, the protection conferred to the invention claimed pursuant to a Swiss-type of claim automatically extends to the products directly obtained through the manufacturing process, the protection conferred by a purpose-limited product claim is broader. *Id.*, § 9.3.

[128] *Id.*, Summary of Facts and Submissions, § V.

[129] Doctors and physicians often recourse to the practice of so called "off-label" prescriptions whenever there is not an on-label alternative on the market or when the off-label use allows for a significant decrease of the sanitary expense for the system. More specifically, the term "off-label" refers to a scenario whereby a certain drug is prescribed for an indication, age group, or in a dosage or route other than those specified in the market authorization and reflected in its official leaflet. An off-label prescription, therefore, does not always corresponds to patent infringement. See R.M. JANSEN, *Off-label use of medications*, in *Legal and Forensic Medicine*, 1610. Notwithstanding the risk it carries for both health and safety of the patients and liability of physicians and pharmacists, this practice is quite spread especially in some medical sectors such as neonatology and paediatry. See C. LENK, G. DUTTGE, *Ethical and legal framework and regulation for off-label use: European perspective*, in 10 *Theapeuthics and Clinical Risk Management* 537, 2014, at 538 and ff. I. VRANCKEN, *Off-label Prescription of Medication*, in 22 *European Journal of Health Law* 165, 2015, 168. Conversely, the term "cross-

practice which happens to be very frequent in the medical field, especially when there happens to be a sensible price difference between the two drugs [130].

In a rather obscure paragraph, the Board held that in the hypothesis of distribution of a medicament containing human acid alpha glucosidase in the 100 to 110 kD form, but packaged and provided with instructions for the use in a treatment *other* than that of infantile Pompe's disease, the likely use of such medicament for the treatment of infantile Pompe's disease would only be "encompassed by the scope" of a purpose-limited product claim, whereas the protection conferred in the form of a Swiss-type of claim would not cover such a use [131]. This very short statement, not supported by any further reasoning, appears devoid of any logic.

Conclusion.

In the past decades, the EPO Chambers have gradually stretched the boundaries of patentable subject matter in the medical field in a way to encompass each and every sliver of inventive activity, including at the very last also dosage regimens. From the perspective of pharmaceutical industries, second medical use inventions in all their forms (from those identifying a specific subclass of patients to be treated to new dosage regimens) cover precious technical advances, whose conception has often requested enormous costs [132], hence

label" is used whenever a certain drug is not simply employed off-label, but when the medicinal product is specifically prescribed or sold for a mode of employment for which, despite not being comprehended in the MA nor in the information leaflet, has been recognized and approved for the underying active ingredient within a different MA (and very much likely, within a different patent). In other words, cross-label refers to the circumstance that the drug is prescribed or suggested for a different but protected therapeutical use. See J. DRESSEL, *Roundtable: The Second Medical Use Challenge*, in 265 *Managing IP*, 26, 2017, 27.

[130] Think about the controversy between the two medicinal products *Avastin* and *Lucentis*, approved for distribution to treat some types of tumors in the first case and otfalmic pathologies in the latter case, where the cross-label use of the latter caused a massive erosion of profits of the former drug, leading the two companies to engage in collusive behaviors aimed at partitioning the market pursuant to their respective MAs. See European Court of Justice of the EU, Grand Chamber, 23 January 2018, case C-179/16, *F. Hoffmann-La Roche Ltd. et al. c. Autorità Garante della Concorrenza e del Mercato*, ECLI:EU:C:2018:25.

[131] *Board of Regents, The University of Texas System/Cancer Treatment*, T 1780/12, 30th January 2014, ECLI:EP:BA:2014:T178012.20140130, r.d. § 9.4.

[132] See C. BERRISCH, *Second medical use claims and scope of protection – A work in progress since 1984*, in *Stockholm Intellectual Property Review*, vol. 2, issue 1, 2019, 38.

deserve to be rewarded with an exclusive right. Scholars however have sometimes perceived some of these titles of protection as "weak" patents, often obtained and then employed to fence off rival companies and to avoid the competitive pressure coming from equivalent products, once patent protection is expired [133]. But beyond the issue of the strategic implementation of patents, which was beyond the topic of this paper, several inconsistencies can be spotted in the EPO approach.

From a systematic point of view, while it may sound plausible to grant absolute protection to the inventor of a new compound patented for a medical application, the above hierarchy in patent strength between structurally new compound first patented for a therapeutical application, first medical use inventions and second medical use inventions does not persuade the reader. As vividly explained by several authors, the balancing of interests intrinsic in all patent laws between private interest of the firm to reap, with an exclusive right, the fruit of its investments in research, and public interest of society towards the advancement of science and technological progress, demands that patent protection be limited to the technical contribution invented [134], disclosed and claimed by the patentee [135]. As applied to the chemical field in general, such principle requires for protection be tailored to both the specific structure *and* the method of use of the compound [136]. Because in chemistry, struc-

[133] See M. FISHER, (nt. 59), at 581. Similarly see D.R. SCHNEIDER, (nt. 26), at 524, pointing at the potential "evergreening" effect that it is likely to happen when second medical indication patents are filed for and obtained by the same patentee. The risk of evergreening is equally evocated, precisely with regard to second medical indication patents, by A. KUR, T. DREIER, *European Intellectual Property Law, Text, Cases & Materials*, Cheltenham UK-Northampton, MA, USA, Edward Elgar Publishing, 2013, at 110.

[134] The principle that breadth of protection be proportionate to the actual increase in knowledge brought about by the patentee with his invention is well established in European patent laws. See V. DI CATALDO, *Questioni in tema di brevetto per formula generale*, in *Nuova giur. civ. comm.*, I, 1991, 554, at 557. G. GHIDINI, (nt. 13), 135.

[135] This view has been expressed by V. Di Cataldo (in, among others, V. DI CATALDO, *Sistema brevettuale e settori della tecnica. Riflessioni sul brevetto chimico*, in *Riv. dir. comm.*, 1985, I, 277 and ff.; *Fra tutela assoluta del prodotto brevettato e limitazione ai procedimenti descritti e agli usi rivendicati*, in *Riv. dir. ind.*, 2004, I, 111; *I brevetti per invenzione e per modello di utilità*, (nt. 5), at 155 and ff.; *Manuale di Diritto Industriale* (with A. Vanzetti), (nt. 27), 438 and ff.) arguing that while only with the advent of new sectors, where multiple uses were conceivable from a given product, specific provisions have been introduced to limit the scope of protection, such limitations should be regarded as implicit to all inventions regardless of the technological sectors, as the system is aimed at rewarding each inventor with an exclusive right which should reflect the ampleness of his inventive effort only.

[136] G. GUGLIELMETTI, *Tutela assoluta e tutela relativa del brevetto sul nuovo composto chi-*

ture and function of the invention are two ingredients bearing exactly the same relevance in the achievement of the desired technical contribution, protection of chemical inventions (especially in the medical field) should always be intended to be purpose-bound, no matter whether the compound is structurally new or not, or whether the compound was or not known to the medical field. Given this assumption, the thorny issue to be solved, specific to the medical field, remains infringement of such purpose-limited product claim inventions, given the circumstance that the structural portions of such inventions often happen to be identical.

The approach of the EPO Chambers, exclusively concerned with patentability issues, purposefully disregarding the impact its decisions would have on infringement, as if scope of protection and counterfeiting were not strictly connected, has been short-sited and much confusion permeates the issue today, as it shown by the very different positions espoused by national Courts [137].

mico, originalità dell'invenzione e dinamiche della ricerca, in *Studi di diritto industriale in Onore di A. Vanzetti, Proprietà Intellettale e Concorrenza*, Tomo I, Milano, Giuffrè, 2004, 765.

[137] For a comparison of the most recent jurisprudence see: M. STIEF, U. ZORR, *Pregabalin and Fulvestrant – A comparison of German and English liability regimes for Swiss-type claims in light of current case law*, in 14 *J. of Intellectual Prop. Law & Practice*, 2019, 487; M. ZIGANN, *Infringement of Swiss-Type Second Medical Use Patent Claims in Germany – Recent Developments in Case Law*, 12 *Wash. J.L. Tech. & Arts*, 245, 2017.