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European Patent Protection for Medical Uses of Known Products and Drug Repurposing

Mateo Aboy, Kathleen Liddell, Matthew Jordan, Cristina Crespo, John Liddicoat

Obtaining European patent protection for medical uses of known products is not a key factor limiting repurposing activity.

Drug repurposing is a strategy for identifying new uses for approved or investigational drugs that are outside the scope of the original medical indications.[1] Finding new therapeutic uses for existing medicines holds significant potential, since it is often faster to develop a drug for a new use if it is already known to be safe and well tolerated by the human body. Repurposing de-risked compounds with previously known therapeutic effects is also an attractive drug development strategy because it can potentially result in lower overall drug development costs and shorter timelines to market introduction.[2] If successful, the public at large benefits from the repurposing of "old" drugs (known products) to treat more common and rare diseases.

An ongoing debate surrounding pharmaceutic repurposing is whether the current intellectual property (IP) regime, particularly with regards to the patent protection for medical uses of known compounds and substances, may be hindering repurposing activity. This debate is taking place on both sides of the Atlantic.[3,4] Commentators often argue that the patent system is failing to provide adequate incentives to promote innovation in the field of drug repurposing—medical use patents, they allege, are too difficult to obtain.[5]

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A. European Patent Protection of Medical Uses of Known Products

The European Patent Convention (EPC) allows for the patent protection of medical uses of known products under Art. 54(4) and Art. 54(5) EPC. This makes it possible to obtain patent protection for repurposed drugs (depending on the context also known as repositioned, re-profiled, or re-tasked drugs). These EPC novelty articles provide an exception from the general principle that product claims can only be obtained for novel products. This is significant because Art.53(c) EPC excludes methods of medical treatment from patentable subject matter. The scope of protection of medical use product claims under Art. 54(5) EPC is limited to the substance or composition for the particular medical use which confers novelty and non-obviousness to the claimed product (i.e., exclusivity extends to the product for use in the treatment of a particular disease or patient cohort).

Beyond subject matter eligibility and novelty, medical use patent claims need to fulfil all other patentability requirements, notably inventive step (non-obviousness). The Art. 54(4) and 54(5) EPC special novelty rule applies solely to substances and compositions. It is not extended to other known products such as medical devices (e.g., wearable, implantable, or ingestible sensors). A product qualifies as a "substance or composition" in the sense of Art. 54(5) EPC if it is the active ingredient or agent in the particular medical use that confers the therapeutic effect that can be ascribed to its chemical properties. Beyond Europe, it is generally possible to protect new repurposed medical uses of known drug molecules in most of the major pharmaceutical markets including the USA and Japan, but in some countries the strategy is to protect a new method of using a known product to treat a disease. An inventive step (or non-obviousness) must also be shown in these countries.

B. Drug Repurposing & Evidence-Based IP Research: Are medical use patents difficult to obtain?

Despite the clear policy importance of developing new treatments faster and more cost effectively, there is limited evidence-based research on the actual patent protection of new medical uses and relatively little is

known about the scale and characteristics of this ongoing patenting activity. In this paper we examine commentators' allegation about patent failure with the overall research question: Is drug repositioning being hindered by the difficulty in obtaining patent protection for medical uses of known products at the EPO?

In a recent study aimed at mapping the European patent landscape for medical uses of known products we showed that, in fact, there is an increasing number of medical use patents being granted at the EPO.[6] This suggested general patent failure for new medical uses was perceived; not actual. That said, several outstanding questions remained to be studied, including those related to 1) the relative difficulty in obtaining patent protection for medical uses of known products in the *strict sense* (i.e., patents for which the broadest independent claim is directed to a medical use) compared to other technical fields, and 2) the characteristics of medical use patents granted by the EPO.

C. IP Questions

More specifically, questions that remain unanswered include: What has been the patenting trend over the last 20 years for medical use patents in the *strict sense*?; Are these patents difficult to obtain (i.e., What is their current grant rate?); How does the number of medical use patents granted per year at the EPO compares to the number of EMA drug authorisations for "new uses of existing medicines"?; Which organizations own these medical use patents?; In how many and what jurisdictions have they been protected?; and What has been the patenting activity by therapeutic area?

Answering these types of questions helps assess the patent protection challenges surrounding drug repurposing, and provide sound evidence-based recommendations. Without more evidence-based IP research to address these types of questions, it is challenging for scholars, legislators, patent offices, and judges to propose, amend, interpret, or apply the law of medical use patents with reasonable chances of achieving desirable social goals such as incentivising drug development across therapeutic areas, including rare diseases.

D. Evidence from Real-World Patent Data

Empirical studies looking at the real-world patenting activity can provide valuable evidence to assess the difficulty of patenting new medical uses in Europe is actual or perceived. For instance, if drug repositioning is being hindered by the difficulty in obtaining patent protection for medical uses of known products, we would expect i) a small number of patents awarded relative to the number of repurposed drug authorisations, ii) a low patent grant rate relative to other technical fields, iii) a lack of coverage for important therapeutic areas, and iv) indications of low value to the owners as measured by metrics of *private value* of these patents.[7]

Conversely, evidence that the patent system is not a key factor limiting repurposing activity would include i) an upward trends in the number of medical use patent grants per year, ii) a high number of patents awarded compared to the number of EMA authorisations for new uses of existing medicines, iii) a comparatively high overall patent grant rate, iv) a broad coverage spanning a wide range of therapeutic areas, and v) private value patent metrics such as the scope of international protection (i.e., family country size representing number of jurisdictions where the patent is granted) and continued payment of maintenance fees for the life of the patents indicating that the owners consider these patents to have strategic IP value.[7]

Search Strategy & Landscaping

We developed a search strategy designed to answer the above questions. The strategy follows the recommendations of Bubela *et al.* on patent landscaping for life sciences innovation[8], as well as the checklist of information for patent landscapes recommended by Smith *et al.*[9] to ensure quality and transparency, but narrowed to answer the specific research questions of this study as opposed to providing a general patent landscape. Similar methodologies have been used to analyze the patent landscape of gene patents[10,11,12] and other medical-related inventions.[10]

A. Identification of Medical Use Patents

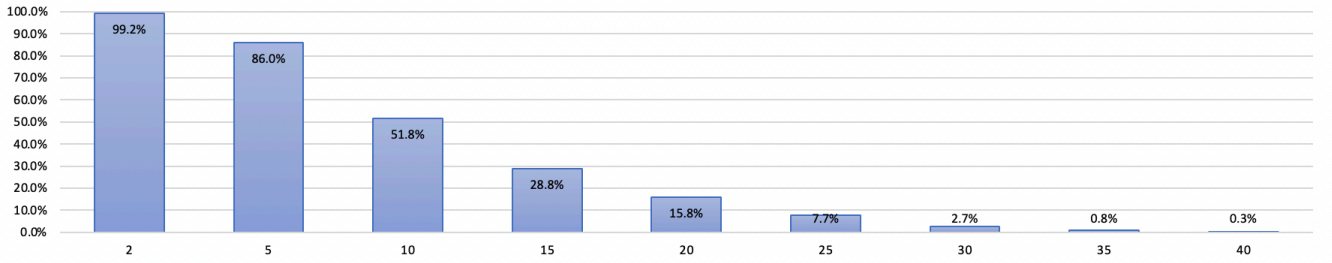
Table 1 provides a summary of the search strategy and results. This strategy is designed to identify patents with claims drafted following the canonical claim formulations for patentable subject matter under the current EPO examination guidance for "medical use of known products".[13] The EPO claim formulation to claim a further medical use for a known product is of the form "Product X *for use* in the *treatment of* […]" This is based on Art. 54(5) EPC.

The search strategy identifies 1) patents with medical use claims (independent or dependent) (**Table 1** Search ID: **S1**), 2) patents where the medical use claim claim language is found in the independent claims (**Table 1** Search ID: **S2**), and 3) patents where the medical use claim is the only independent claim in the patent (**Table 1** Search ID: **S2**).

Searches **S1-S3** identify granted patents (DT: G) in the last 20 years containing the medical use language claims. The search achieves a high degree of specificity by requiring the claims to contain the exact EPO canonical claim language "for use in the treatment of" and further narrowing the subclass to CPC A61 (medical uses). A similar patent search strategy was previously used

Table 1 - Summary of search strategy and results (Patent Office: EPO, Search Date: 2021-04-14)

Search ID	Search Concept	Search Query	No. Patents	Results
S1	Medical use patents with EPC2000 claims	((ACLM:"for use in the treatment of")) AND CPC:A61 AND DT:G AND ISD:([2000-01-01 TO 2020-12-31])	11,994	
S2	Medical use patents with EPC2000 independent claims	((ICLM:"for use in the treatment of")) AND CPC:A61 AND DT:G AND ISD:([2000-01-01 TO 2020-12-31])	4,086	34%
S3	Medical use patents where the EPC2000 claim is the only independent claim on the patent	S2 AND ICLM_CT:1	1,590	
S4	S3 where the family country count is >2	2 S3 AND SFAM_CC_CT:[2 to *]	1,577	99.2%
S5	S3 where the family country count is >5	5 S3 AND SFAM_CC_CT:[5 to *]	1,367	86.0%
S6	S3 where the family country count is >10	10 S3 AND SFAM_CC_CT:[10 to *]	823	51.8%
S7	S3 where the family country count is >15	15 S3 AND SFAM_CC_CT:[15 to *]	458	28.8%
S8	S3 where the family country count is >20	20 S3 AND SFAM_CC_CT:[20 to *]	252	15.8%
S9	S3 where the family country count is >25	25 S3 AND SFAM_CC_CT:[25 to *]	122	7.7%
S10	S3 where the family country count is >30	30 S3 AND SFAM_CC_CT:[30 to *]	43	2.7%
S11	S3 where the family country count is >35	35 S3 AND SFAM_CC_CT:[35 to *]	13	0.8%
S12	S3 where the family country count is >40	40 S3 AND SFAM_CC_CT:[40 to *]	4	0.3%
S12	S7 patents now expired	S7 AND DOC_STATUS:INACTIVE	58	4%



to map the European patent landscape of medical uses of known products.[6]

B. Identification of "valuable" Medical Use Patents

The expected *private value* of a patent application (a priori estimate as judged by the patent owners) correlates with the investment they are willing to make to secure maximum protection. The investment (cost) of a patent application scales with the size of the patent family, especially with the number of countries where the patent application is filed. Accordingly, the patents deemed more valuable by the their owners are filed and prosecuted to allowance in more jurisdictions (i.e., the expected/estimated value is correlated with the number of jurisdictions in which protection was achieved) and maintenance fees continue to be paid in order to keep the patents in force.[7]

The results of search **S3** —granted EPO medical use patents in the last 20 years where the only independent claim contains the canonical claim language for medical uses of known products— were used as the input for search strategies (**S4**-**S12**) designed to analyze the number of jurisdictions where the patent was obtained.

C. Expert Review & Classification of Patenting Activity by Disease

We selected the top 15% medical use patents in terms of the number of jurisdictions filed and granted (Search ID: **S8**) for further detailed analysis involving manual expert review and classification of the patent activity by disease. The 252 medical use patents where the EPC 2000 claim is the only independent claim and with families spanning 20 or more countries (**S8**) were manually reviewed by two experts (MJ and JL). The purpose of the review was to classify the patents according to the therapeutic area, and to confirm the absence of any false positives in the patent search algorithm used for the automatic landscaping results.

Each patent was analyzed to identify the medical conditions or diseases named in the independent EPC 2000 claim. The first named condition in the independent claim was searched for in the U.S. National Library of Medicine's Medical Subject Headings (MeSH) Browser. If the first named disease (as claimed in the patent) was not recognised by MeSH, the subsequent listed conditions were searched until a match was found.

MeSH situates diseases within 'tree structures' of increasing granularity, with the highest level on each 'tree' denoting its therapeutic area. Once the relevant tree structure was identified, the patent was classified according to the most general level of abstraction (the broadest possible classification). When a condition was listed in multiple tree structures, the patent was reviewed holistically to allow for a final classification which is consistent with the content of the patent as a whole.

All but two patents were classified using the highest level on the MeSH

tree. These patents had claims directed to the treatment of 'soft tissue calcification associated with chronic kidney disease' and 'overactive bladder'. The reason these patents could not be classified using the highest MeSH categories is that the most appropriate therapeutic areas were 'male urogenital diseases' and 'female urogenital diseases and pregnancy complications' but holistic review of the patent claims found they were not drafted to be gender-specific. Consequently, these patents were classified according to the broadest category common to both trees, namely 'urologic diseases'.

In total, the 252 patents spanned 23 categories with distinct disease codes. No false positives were identified during the expert review. All the patents identified by the automatic patent search algorithm contained a single independent claim directed to medical uses of known products. The lack of false positives during the expert review of 252 patents indicates that the estimated specificity of the search algorithm is at least 99.6%. This makes it suitable to generate patent landscape results on the larger datasets such as **S1-S3**.

Landscape Results & Discussion

The output of the search strategy was analyzed further using patent analytics to answer the research questions.

1) What has been the patenting trend over the last 20 years for medical use patents and what is their current grant rate?

Our search strategy (**S1**) yielded 11,994 patent with claims directed to medical uses of known products (EPC2000 claims) in the last 20 years. Of these, 4,086 (34%) contain the EPC2000 canonical claim language on an independent claim (**S2**) and in 1,590 the medical use language is included in the sole independent claim.

A. There is an Increasing Number of Medical Use Patents Per Year

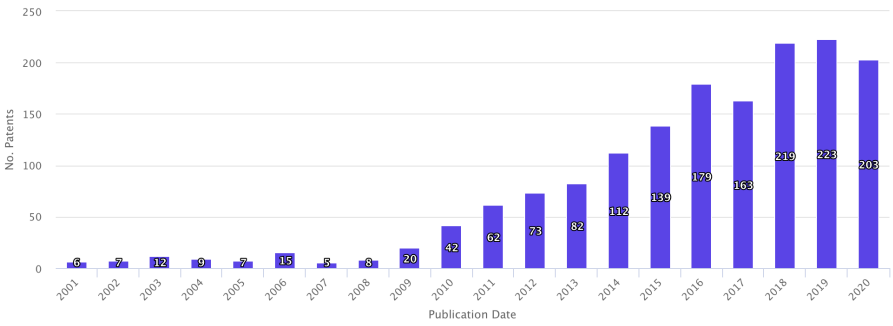


Fig. 1 EPO medical use patents with independent claims directed to medical uses of known products from 2001 to 2020 plotted by publication date of the patent grant (Search ID: **S3**). Since 2018 the EPO is granting over 200 medical use patents per year. The number of patent grants per year exceeds the number of repurpose drug market authorizations by an order of magnitude. This indicates that obtaining European patent protection for medical uses of known compounds or substances is not the factor limiting repurposing activity.

Fig. 1 shows the granted medical use patents where the medical use language is contained on the broadest claim of the patent (**S3**) from 2000 to 2020. This figure indicates that there has been a substantial upward trend in the last 10 years (since 2010) for patents with EPC2000 independent claims.

B. The Number of EPO Medical Use Patents Substantially Exceeds the Number of Repurposing Drug Authorisations

Since 2018 the EPO is granting over 200 medical use patents per year. The number of patent grants per year substantially exceeds the number of EMA market authorizations "for new uses of existing medicines". Since 2016, the EMA has authorised between 27 and 42 new active substances. Between 2016 and 2020 the EPO granted 987 medical use patents in the *strict sense* (see **Fig. 1**) -with the sole independent claim using the EPC2000 canonical claim formulation for medical uses of known products. During the same period the EMA authorised 318 new uses for existing medicines (EMA Human Medicines Hightlights 2016-2020). Thus, there are 3 times more new use patent grants (even when considering the narrowest definition of new use patent -i.e., only counting those having the exact EPO2000 canonical language on the single independent claim of the patent **S3**) than new use authorisations of existing medicines (even when considering the broadest definitions of new use authorisation -i.e., including extension of patient populations). Based on **S2** (EPO 2000 canonical language in at least one independent claim) the factor is 8X and for **S1** is 22X. This indicates that obtaining European patent protection for medical uses of known compounds or substances is not the factor limiting repurposing activity.

C. Medical Use Patents have Relatively High Allowance Rates at the EPO

The relative proportion of granted applications to the total number of applications for years with no (or minimal number of) pending applications indicates the patent allowance rate has steadily increased from 43% in 2011 to 61% in 2015 for **S1**, from 49% to 64% for **S3**, and from 68% to 85% for **S8.** For comparison, the EPO President Battistelli reported at the 30th Annual US Bar-EPO Liaison Council Meeting in 2014 that EPO patents are granted in 49% of total filings.

In this study we find that patents where the medical use claim is the sole independent claim (i.e., medical use patents in the *strict sense*) (**S3**) have a higher patent grant rate than patents with independent claims

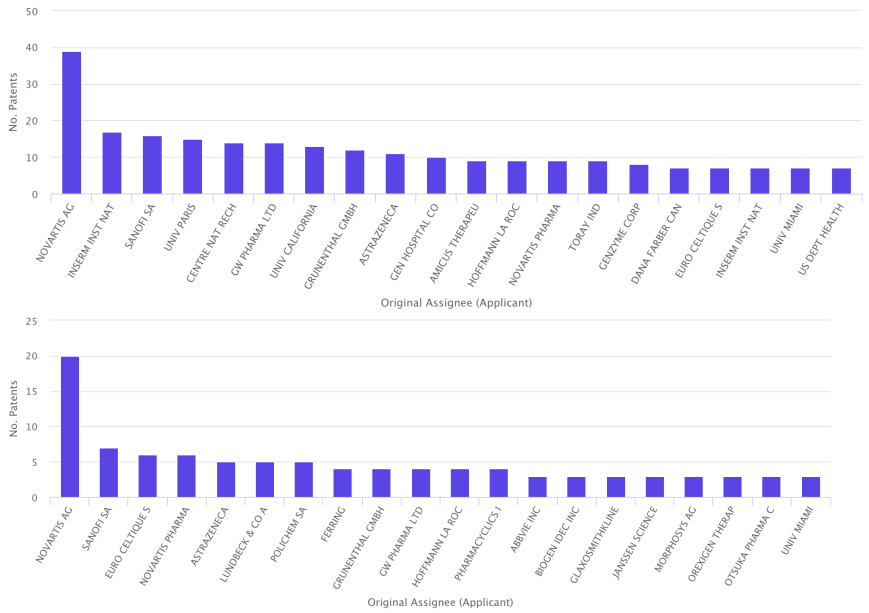


Fig. 2 Organizations with the highest count of patents with EPO medical use independent claims (**S3**, top plot) and organizations owning medical use patents with family country counts of at least 20 jurisdictions (**S8**, bottom plot) in the last 20 years. The result indicates that while universities and research institutes are active in protecting medical use inventions (top plot) the majority of patents protected in 20 or more jurisdictions are owned by pharmaceutical companies.

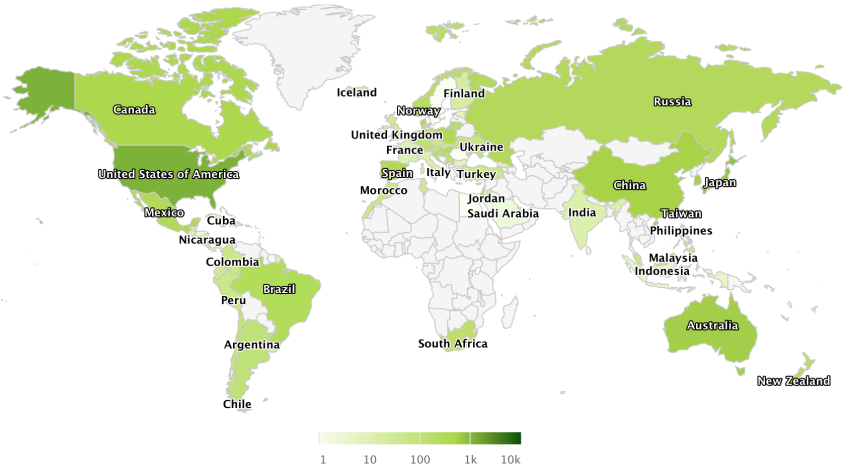


Fig. 3 Jurisdictions where patents in the same simple patent family as **S8** are protected (the collection of patent documents considered to cover the same invention and all having exactly the same priorities as the **S8** EPO medical use patent). The top 10 patenting jurisdictions for the EPO medical use simple patent family are: USA, Japan, Australia, Republic of Korea, China, Canada, Russia, Mexico, Brazil, Hong Kong.

directed to compounds (based on **S1**) or the overall EPO grant rate (i.e., across all technical fields). Furthermore, the medical use patents identified as "most valuable" (**S8**) (i.e., representing the top 15% in terms of country grants) had a relatively high grant rate (85%).

D. Claims Strategies

The results of this study show that approximately 34% of patents include an independent EPC2000 claim **(S2)**, and that this proportion has been relatively consistent for the last 20 years. This result is consistent with our previous study where our expert review results showed that that EPC2000 medical use claims were the independent claim in 31.6% of the cases,[6] corresponding to patent protection for drug repurposing activity. Conversely, in approximately 70% of the cases, patent applications for novel products also claimed the medical use in the same application (**S1**). As previously noted,[6] the special novelty rule in Art. 54(4) and Art. 54(5) EPC provides an incentive to disclose medical uses for novel products, since if not claimed along with their novel product (or otherwise made available to the public), third parties could use the special rule to obtain patent protection (and associated exclusivity) for first or further medical uses. Thus, patent applicants draft independent claims to protect the product for all uses (e.g., medical or non-medical) and EPC2000 canonical claim language in dependent claims to specifically prevent third parties from obtaining the medical use claims through the special novelty rules). Overall, the special novelty rules of Art. 54 EPC incentivises early disclosure of medical uses. At the EPO it is generally possible for applicants to simultaneously discloses more than one "subsequent" therapeutic use under Art. 54(4) EPC in a single application. Multiple medical use claims directed to different uses are allowable as part of the same application, provided they form a single general inventive concept (Art. 82 EPC).

2) Which organizations own these medical use patents?

The results of the patent search were analyzed to determine which organizations are leading the patent activity for further medical uses. **Fig 2** provides a summary of these results, showing the 20 top current assignees (patent owners) with the

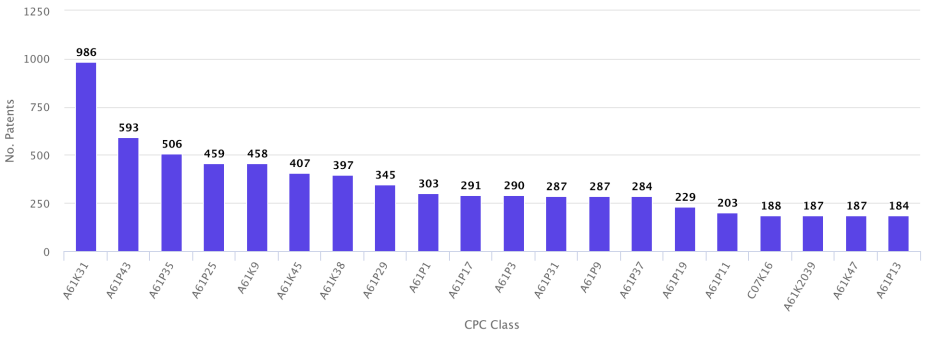


Fig. 4 Number of EPO medical use patents by CPC (Cooperative Patent Classification) class. Legend: A61K31 (Medicinal preparations containing organic active ingredients), A61P35 (Antineoplastic agents), A61P25 (Drugs for disorders of the nervous system), A61P29 (Non-central analgesic, antipyretic or anti-inflammatory agents, e.g antirheumatic agents; Non-steroidal anti-inflammatory drugs (NSAIDs), A61P1 (Drugs for disorders of the alimentary tract or the digestive system), A61P17 (Drugs for dermatological disorders), AP61P3 (Drugs for disorders of the metabolism), A61P31 (Antiinfectives, i.e. antibiotics, antiseptics, chemotherapeutics), A61P9 (Drugs for disorders of the cardiovascular system), A61P37 (Drugs for immunological or allergic disorders), AP61P19 (Drugs for skeletal disorders), A61P11 (Drugs for disorders of the respiratory system), and A61P13 (Drugs for disorders of the urinary system). A61P43 is a residual category for drugs for specific purposes not provided for in groups A61P1-P41.

highest count of patents with EPO medical use independent claims (**S3**, top plot) and organizations owning medical use patents with family country counts of at least 20 jurisdictions (**S8**, bottom plot) in the last 20 years. The result indicates that while universities and research institutes are active in protecting medical use inventions (top plot) the majority of patents protected in 20 or more jurisdictions are owned by pharmaceutical companies.

Universities and publicly funded research institutes are playing an important inventive role in drug repurposing[14], but budgets and technology transfer policies required a more targeted patent protection strategy (e.g., USA and EPO protection) unless a licensee who can cover the prosecution and maintenance costs is identified at early in the patenting process.

3) In how many and what jurisdictions have these medical use patents been protected?;

Table 1 shows the majority (99.2%) of the medical patents are protected in at least 2 jurisdictions (EPO and USPTO). The results of searches **S4** to **S12** indicate that less than half of the patents are protected in 10 or more jurisdictions (EPO counting as one jurisdiction). The top 15% of these patents (n=252) were granted in 20 or more jurisdictions. **Fig. 3** shows the jurisdictions where the "most valuable" EPO medical use inventions are protected. Specifically, it shows the jurisdictions where patents in the same simple patent family corresponding as **S8** are protected. The top 10 patenting jurisdictions for the patent family are: USA, EPO, Japan, Australia, Republic of Korea, China, Canada, Russia, Mexico, Brazil, Hong Kong. While a simple patent family is the collection of patent documents considered to cover the same invention and all having exactly the same priorities, the claim language differs as it is adapted to the practice in the particular jurisdiction. For instance, in the USA second medical use patents are often protected using a method of treatment claim, in China and Brazil are Swiss-style claims, and Japan allows a number of different formats including Swiss-type and EPC2000 canonical claims.[15]

A patent that has been granted by the EPO may subsequently be made effective in any of the countries for which a designation, extension or validation fee has been paid (e.g., Germany, United Kingdom, France, Switzerland, Belgium, Ireland). This process is commonly known as "validation" of the European patent. Some countries require a full translation of the entire patent (specification, claims, and sequence listing if present) with the national patent office as part of the validation procedure and count as a separate jurisdiction, these include Spain, Portugal, Italy, and Slovakia (**Fig. 3**).

Table 1 shows (**S12**) the survival rate for medical use patents with a simple family country count of 15 of grants (representing the top 30%): 96% of the patents granted in the last 20 years are still in force (i.e., only 4% have expired or have been abandoned). The results show that the majority of owners of these patents continue to pay the maintenance fees for the duration of the patent term, indicating that they consider their medical use patent portfolios to have strategic private value.

4) What has been the patenting activity by therapeutic area?

A. Automatic Patent Landscape Analysis based on CPC Subclass

Fig. 5 shows the number of EPO medical use patents by CPC (Cooperative Patent Classification) class. The majority of the patents are classified under A61K31 (Medicinal preparations containing organic active ingredients). When classified by the specific therapeutic activity (A61P) the top therapeutic areas are: A61P35 (Antineoplastic agents), A61P25 (Drugs for disorders of the nervous system), A61P29 (Non-central analgesic, antipyretic or anti-inflammatory agents, e.g antirheumatic agents; Non-steroidal

Disease	Number
Neoplasms [C04]	53
Pathological Conditions, Signs, and Symptoms [C23]	27
Nervous System Diseases [C10]	23
Infections [C01]	22
Nutritional and Metabolic Diseases [C18]	17
Skin and Connective Tissue Diseases [C17]	16
Mental Disorders [F03]	11
Respiratory Tract Diseases [C08]	11
Musculoskeletal Diseases [C05]	10
Eye Diseases [C11]	8
Chemically-Induced Disorders [C25]	7
Hemic and Lymphatic Diseases [C15]	7
Immune System Diseases [C20]	7
Digestive System Diseases [C06]	6
Animal Diseases [C22]	5
Female Urogenital Diseases and Pregnancy Complications [C13]	5
Male Urogenital Diseases [C12]	4
Cardiovascular Diseases [C14]	3
Wounds and Injuries [C26]	3
Endocrine System Diseases [C19]	2
Congenital, Hereditary, and Neonatal Diseases and Abnormalities [C16]	2
Urologic Diseases [C12.777] / [C13.351.968]	2
Stomatognathic Diseases [C07]	1

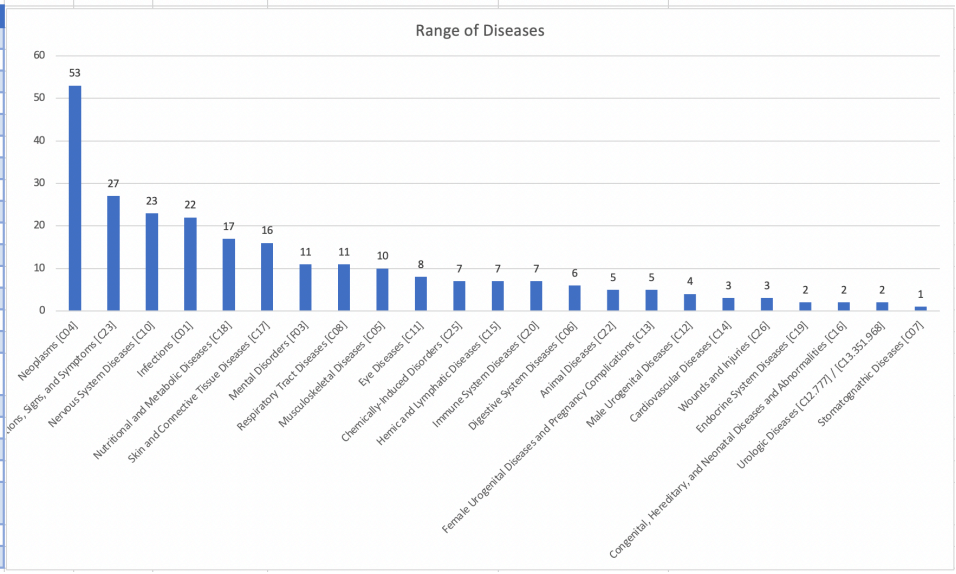


Fig. 5 Results of expert review manual classification of medical use patents based on the disease claimed on the broadest independent claim. The first named condition on the independent claim was classified based on the U.S. National Library of Medicine's Subject Headings (MeHS). The top specific diseases for EPO medical use patents with families in 20 or more jurisdictions are Neoplasms (C04) and CNS (C10). This matches the results obtained using the CPC analysis (Fig. 5).

anti-inflammatory drugs (NSAIDs)), A61P1 (Drugs for disorders of the alimentary tract or the digestive system), A61P17 (Drugs for dermatological disorders), AP61P3 (Drugs for disorders of the metabolism), A61P31 (Antiinfectives, i.e. antibiotics, antiseptics, chemotherapeutics), A61P9 (Drugs for disorders of the cardiovascular system), A61P37 (Drugs for immunological or allergic disorders), AP61P19 (Drugs for skeletal disorders), A61P11 (Drugs for disorders of the respiratory system), and A61P13 (Drugs for disorders of the urinary system). A61P43 is a residual category for drugs for specific purposes not provided for in groups A61P1-P41.

When classified according to the chemistry, C07 (Organic Chemistry) is the top class with C07K (Peptides) the most prevalent subclass. A patent may be classed in multiple classes. For instance, a given patent may be classified as A61K denoting that the patent relates to a medicinal preparation containing organic ingredients and A61P35 with specific therapeutic activity as an antineoplastic agent.

B. Expert Classification

Fig. 6 shows the results of expert review manual classification of medical use patents based on the disease claimed on the broadest independent claim. The first named condition in the independent claim was classified based on the U.S. National Library of Medicine's Subject Headings (MeSH). The top specific diseases for EPO medical use patents with families in 20 or more jurisdictions are Neoplasms (C04) and Nervous Systems Diseases (C10). This generally matches the results obtained using the CPC analysis (**Fig. 5**). Our results show a broad coverage of patent activity spanning therapeutic areas.

Conclusions

There are currently over 4,086 patents with independent claims directed to medical uses of known products. Of these, in 1,590 (38.9%) patents the only independent and broadest claim in the patent is directed to a medical use of a known product. Most of these patents (99.2%) are protected in Europe (EPO) and the USA (USPTO).

Since 2018 the EPO has been granting over 200 new medical use patents per year (over 600 patents since 2018). The top 15% of the medical use patents are protected in 20 or more jurisdictions (with the EPO counting as one). While universities and publicly-funded research institutes are active in protecting medical use inventions, the majority of patents protected in 20 or more jurisdictions are owned by pharmaceutical companies.

The top specific diseases for EPO medical use patents with families in 20 or more jurisdictions are cancer (MeSH C04) and diseases of the nervous system (MeSH C10). That said, our our results show a broad coverage spanning a wide range of therapeutic areas.

Our finding that the number of in-force medical use patents is substantially higher than the corresponding number of repurposed drugs receiving EMA/FDA market authorizations suggest that contrary to what other commentators have indicated, difficulty in obtaining patent protection for inventive activity involving second medical uses on known substances does not appear to be the key challenge or a bottleneck affecting repurposing activity. Furthermore, the majority of owners of these patents continue to pay the maintenance fees for the duration of the patent term, indicating that they

consider their medical use patent portfolios to have strategic private value. It appears that even if the medical use patents are not protecting a current repurposed drug with market authorization the owners consider them of enough strategic long-term value to continue paying the maintenance fees, perhaps because it may protect forthcoming repurposed drugs in their pipeline.

In summary, we find 1) an increasing number of medical use patents relative to the number of repurpose drug authorisations, 2) a relatively high grant rate for medical use patents indicating a clear legal basis for subject mater eligibility under EPC54(5), 4) diversity of patent owners obtaining these medical use patents (public and private), 5) diversity of jurisdictions where they are protected, and 6) coverage among the major therapeutic areas. These findings indicate that obtaining patent protection for medical use inventions at the EPO does not appear to be a major challenge and it is likely not hindering drug repurposing.

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Competing interests

The authors declare no competing interests.

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