Drug Repurposing Guidebook

Building Block I444

This document defines the content of the FACT SHEET to be created for each identified tool, incentives, initiative or practice (the Building Block) introduced by public bodies or used by developers to expedite drug repurposing in Rare Diseases (RDs).

ITEM	DESCRIPTION
Building Block (BB) Title	**How to search and use IP and legal databases**
References	**[1]** Arora A et al., 2017. *Papers to patents*. Nature. 552: S10. https://www.nature.com/articles/d41586-017-07421-3 **[2]** Rotolo D el al., 2022. *Why do firms publish? A systematic literature review and a conceptual framework.* Research Policy. 51:104606. https://www.sciencedirect.com/science/article/pii/S0048733322001299 **[3]** Smith J et al., 2017. *Evidence of insufficient quality of reporting in patent landscapes in the life sciences*. Nat Biotechnol. 35:210-4. https://www.nature.com/articles/nbt.3809 **[4]** Krauß J and Kuttenkeuler D, 2021. *When to file for a patent? The scientist's perspective.* N Biotechnol. 60:124-9. https://www.sciencedirect.com/science/article/pii/S1871678420301849 **[5]** Donald K et al., 2018. *Tips for reading patents: a concise introduction for scientists*. Expert Opin Ther Pat. 28:277-280. https://www.tandfonline.com/doi/full/10.1080/13543776.2018.1438409 **[6]** Krauß J and Kuttenkeuler D, 2018. *Intellectual property rights derived from academic research and their role in the modern bioeconomy-A guide for scientists*. N Biotechnol. 40:133-9. https://www.sciencedirect.com/science/article/pii/S1871678416326450 **[7]** Dias C and Almeida R, 2013. *Scientific production and technological production: transforming a scientific paper into patent applications*. Einstein. 11:1-10. https://www.scielo.br/j/eins/a/RxYC4VQftCzNGsXcfzpW3Mj/?format=pdf&lang=en **[8]** Southan C, 2020. *Opening up connectivity between documents, structures and bioactivity*. Beilstein J Org Chem. 16:596-606. https://www.beilstein-journals.org/bjoc/articles/16/54 **[9]** Senger S, 2017. *Assessment of the significance of patent-derived information for the early identification of compound-target interaction hypotheses*. J Cheminf. 9:26. https://jcheminf.biomedcentral.com/articles/10.1186/s13321-017-0214-2

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	[10] Krallinger M et al., 2017. *Information Retrieval and Text Mining Technologies for Chemistry*. Chem Rev. 117:7673-7761. https://core.ac.uk/download/pdf/87660278.pdf **[11]** Barbieri M, 2022. *Patent Prior Art Searches: Basic Principles and Strategies*. Preprints 2022, 2022050054. https://www.preprints.org/manuscript/202205.0054/v1 **[12]** Van Rijn T e Timmins J, 2023. *Patent landscape analysis—Contributing to the identification of technology trends and informing research and innovation funding policy*. Microbial Biotech https://ami-journals.onlinelibrary.wiley.com/doi/10.1111/1751-7915.14201 **[13]** Patentscope help page https://patentscope.wipo.int/search/en/help/help.jsf **[14]** Lens Patents Help page https://support.lens.org/article-categories/patent/ **[15]** Google Patents https://support.google.com/faqs/answer/7049475?hl=en **[16]** IPC patent classification search engine https://ipcpub.wipo.int/ **[17]** CPC patent classification search engine https://worldwide.espacenet.com/patent/cpc-browser **[18]** Pubchem Docs (help page) https://pubchemdocs.ncbi.nlm.nih.gov/about **[19]** Kim S et al., 2022. *PubChem 2023 update*. Nucleic Acids Res. gkac956. https://doi.org/10.1093/nar/gkac956 **[20]** DrugBank https://go.drugbank.com/drugs **[21]** Zhou Y et al., 2022. *Therapeutic target database update 2022: facilitating drug discovery with enriched comparative data of targeted agents*. Nucleic Acids Res. gkac95. https://academic.oup.com/nar/article/50/D1/D1398/6413598 **[22]** Avram S et al., 2022. *DrugCentral 2023 extends human clinical data and integrates veterinary drugs*. Nucleic Acids Res. gkac1085. https://doi.org/10.1093/nar/gkac1085
Description	Even a quick analysis of literature shows, on one side, the progressive growth in scientific publishing activities reporting the content of patent literature that is relevant for developing and using drugs, but, on the other side, the quite limited (if not biased) understanding of the patent system by many authors who do not evaluate correctly the actual relevance of patent-related issues for evaluating, accessing and using drugs, in particular with respect to rare diseases. Moreover, there are sparse but clear evidences that, while several companies have reduced their scientific publishing activities (preferring to disclose such information only or, early on, in own patent publications [1,2]), the quality of reports summarizing the content of patent publications in scientific literature is quite uneven [3]. Indeed, only few PubMed-indexed articles try conveying basic information about the patent system and the content of patent documents to the academic audience [4-7], while the opportunities to perform extensive analysis across patent and scientific literature are growing, in particular for medicinal chemistry topics

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	relevant for drug repurposing [8-12]. Thus, it is important to provide investigators with a guidance about how to effectively extract and evaluate findings from patent literature, to be combined with findings from biomedical literature in order to elaborate work hypotheses for selecting candidate drugs to be repurposed in a rare disease and evaluate how testing such compound(s) in models or patients. This BB provides investigators with an overview of some basic concepts about patent documents and data (application Vs grant, priority Vs final filing, technical disclosure Vs claims, geographical Vs commercial scope, patent classification codes, patent maintenance, claims categories, etc.) and details about using most effective free databases indexing patent information (coverage, search strategies, data extraction/ archiving, programmatic access, etc.), proposing simple case studies for - Patent-only databases such as Patentscope [13], Lens Patents [14], Google Patents [15], and related Patent Classification search engines [16-17]; and - Public databases indexing patent, scientific, and regulatory information for chemical compounds [18-22].
Category	Contact with TTO and Patents
Type of BB	Development practice
Geographical scope	International
Availability	It covers information resources are freely available (unless indicated otherwise, in particular for copyright reasons or subscription-based access).
Scope of use	Support to investigators involved in Drug Repurposing & Rare Disease research by avoiding duplicated efforts and improving the process for selection & (pre)clinical validation of drug candidates by: - Increasing awareness about the (pre)clinical information that is available in patent literature; - Correcting some common opinions and practices about patent activities for pursuing (pre)clinical research activities; and - Improving the practices about the use of databases of patent literature and the extraction of information and data from patent publications.
Stakeholders involved	Investigators involved in (pre)clinical research activities and data analysis; patients' organizations; technology transfer offices (TTOs) and business development professionals within academic institutions, agencies and companies that work in the fields of drug development, regulatory affairs, and health policy.
Enablers/ Requirements	Previous experience in: - use of internet resources for scientific research and literature;

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	- drug and/or rare disease research, clinical, Technology Transfer, or regulatory activities.
Output	Useful knowledge for a faster selection, validation, and access to new therapeutic strategies in rare diseases by: - taking full advantage of (pre)clinical evidences already available; and - better understanding patent rights and obligations that apply to commercially available drugs.
Best time to apply and time window	This BB is mainly applicable in the early phases of drug development, to gather all relevant information before/during the process for selection & (pre)clinical validation of drug candidates but it can support activities also in later steps, before taking any major commitment or decision when pursuing the regulatory proceedings and facilitating the access to the selected drug (acquisition, distribution, manufacturing, clinical use, safety, reimbursement).
Expert tips	PROs: - Growing examples in the scientific literature and extensive support can be found in the cited websites; - NO copyright issues apply to patent documents. CONs: - A regular use of the described databases and search strategies is needed to consolidate the knowledge and skills based on this BB; - Some commercial databases are more effective than those described but their access and use require more resources; - Non-English languages can be used in patent literature, thus translation tools may be needed; - Patent databases, patent classification, and some patent/legal provisions may evolve over time and guidance may become incomplete/incorrect; - The patent information that is identified using the guidance in the BB needs to be evaluated by specialists in legal proceedings at national level (since many patent rules and other legal provisions applicable to drugs may differ at the country level) and in strategic management before taking any major commitment or decisions related to intellectual property and avoiding to be over-confident in such matters.