Process on Corporate Responsibility in the Field of Pharmaceuticals
Platform on Access to Medicines in Developing Countries with a Focus on Africa

Working Group on Patent Information

Final Report

October 2013

Summary

In the field of patents and medicines, many organisations have expressed the need for more transparent and accessible public patent information, including finding the most relevant patent documentation, identification of patent holders, patent family members in different countries, and legal status. Both the technical information contained in the patents, as well as the scope of patent protection, have implications for further research and development, as well as for global use of the medicines. There is also a perceived necessity to customise and optimise the patent information services to meet the special needs in this critical field.

The objective of this Patent Information Working Group was to facilitate access to patent information in the field of medicines which are of particular interest to enterprises operating in developing countries (such as in sub-Saharan Africa) through a dedicated customisation of the patent information system in this area.

Discussions in the Working Group highlighted the complexity of the subject, as well as the very different viewpoints of the diverse stakeholders represented. To help clarify the requirements of users, and match these with the capabilities of potential providers, the group agreed in November 2012 to reduce the scope of the exercise to a pilot project involving one compound identified by potential users (Global Fund, MSF, MPP), namely GS7977, a Hepatitis C pipeline drug, with the international non-proprietary name Sofosbuvir.

The European Patent Office conducted an initial pilot exercise to indicate how the patent information services could be suitably customised; these results were further enhanced by a UK-based consultancy, CambridgeIP.

The final outcome of the Group's work is the attached paper analysing the findings/challenges/costs experienced in the pilot project, and the potential feasibility of a fully-fledged project.

The consensus emerging is that it is possible to significantly enhance the transparency of, and access to relevant patent information in this medical area. The results obtained have been discussed with potential users, who have indicated how these initial outcomes could be further improved.

On 13 December, a follow-up to the first pilot has been completed. A finer classification has been applied to the original results together with the results of an updated search (27/11/2013), as requested by the potentially benefiting stakeholders. The final outcome needs to be reviewed and verified and an update of this document is expected to come in due course.

The key recommendation is to further extend this pilot to include up to 6 further compounds and to verify the results and resources required across a wider range of compounds.

Furthermore, a clear definition of the final scope of the initiative in terms of the range of compounds and coverage of countries is required, as well as the final presentation form of the customised and enhanced patent information system.

Given the nature of this project, it has to be explored whether other Commission services / international organisations / institutions would be interested in following up on the results of the pilot project.

1. Introduction – The framework

Health is one of the fundamental rights of every human being. It plays a major role in the development of a society and its citizens; it makes a substantial contribution to improving the living conditions. This is particularly true in developing countries where access to medicines is one of the main obstacles in improving public health.

The European Commission's Vice-President Antonio Tajani, responsible for Industry and Entrepreneurship, launched in September 2010 the **Process on Corporate Responsibility in the Field of Pharmaceuticals** (Process). The initiative aimed at facilitating discussions on improved access to medicines, ethics and transparency in the sector.

The Process consisted of three platforms (work streams):

- Access to medicines in Europe
- Ethics and transparency
- Access to medicines in developing countries with a focus on Africa

In its Conclusions on Innovation and Solidarity in Pharmaceuticals, in December 2010 the Council of the European Union invited the European Commission and the Member States to "foster dialogue with stakeholders on: […] access to medicines in developing countries, with a focus on Africa, particularly by cooperating in the process of corporate responsibility in the field of medicinal products".

Based on this mandate, the goal of the platform **Access to Medicines in Developing Countries with a focus on Africa** was to reflect on the contribution Europe can make, the value-added of industry's involvement and the challenges society, governments and industry are facing. The added value of the initiative consists in the more effective involvement of the European pharmaceutical industry. This initiative enhanced collaboration between governments, international organisations, pharmaceutical companies and civil society so as to discuss activities which are aimed at improving access to quality medicines in resource restricted parts of the world.

According to its Terms of Reference[1], the Project Group on Patent Information[2] aims at facilitating better access to relevant patent information needed for medicines which are of particular interest to developing countries, with a special focus on sub-Saharan Africa.

As mentioned previously, regarding public patent information (such as identification of patent holders and patent families in different countries), transparent and accessible data is needed as it has implications for research, development and procurement of the medicines. The objective of the group was therefore to improve the availability and access to patent information through expert search and analysis of augmented patent data. The establishment of a database of expert reviewed, indexed and classified patent information was considered by the group as discussed below.

2. Background and context

A key function of the patent system is to disclose technical information to the public through the publication of patent applications which disclose how to carry out proposed inventions. If and when granted, the final patent specification is published to indicate the actual scope of the exclusive rights claimed. However, not all patent offices make published applications available in on-line databases. In addition, it is often very difficult to identify which patents relate to which medicines or active ingredients due to complex technical language used, and whether such patents have been filed or granted and remain in force in particular countries, especially developing countries. This information is required by any enterprise wishing to know the scope of patent protection in one country, and what exclusive rights (if any) they might risk infringing.

This situation is not optimal with regard to public health and access to medicines. Lack of information on what is patented as well as on the expiry date or general legal status of patents and patent applications in particular countries may lead to sub-optimal decisions by a variety of players ranging from ministries responsible for health to procurement agencies, R&D institutions or domestic pharmaceutical companies.

The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, adopted by WHO Member States in 2008, recognized the importance of "facilitate widespread access to, and promote further development of, if necessary, compiling, maintaining and updating, user-friendly global databases which contain public information on the administrative status of health-related patents, including supporting the existing efforts for

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1 http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform-africa/index_en.htm

2 The members of the Project Group on Patent Information were: European Patent Office (EPO), World IP Organisation (WIPO), World Health Organization (WHO), Medicines Patent Pool (MPP), Medicines Sans Frontieres (MSF), Global Fund, European Generic Medicines Association (EGA), European Federation of Pharmaceutical Industries and Associations (EFPIA), European Association for Bioindustries (EuropaBIO), International Federation of Pharmaceutical Manufacturers & Associations, Germany.

determining the patent status of health products"[3]. The recent WHO, WIPO, WTO Study *Promoting Access to Medical Technologies and Innovation*[4] describes the importance of patent information for medicines, particularly for procurement. Also the summary of a WHO, WIPO, WTO Joint Technical Symposium on Access to Medicines, Patent Information and Freedom to Operate highlights that:

"*Procurement agencies would benefit from tools to aid the search for patents relating to health technologies, as well as a consultation service on how to find and interpret patent information*"[5].

Since the Informal Workshop on "Access to medicines in developing countries with a focus on Africa: How can the European industry contribute?", which was convened by DG Enterprise on 14 and 15 March 2011, there has been some progress in enhancing patent transparency in relation to medicines in developing countries that are worth noting.

In April 2011, the Medicines Patent Pool issued its Patent Status Database on Selected HIV Medicines. The database enables access to information on the patent status of 25 antiretroviral medicines in about 80 countries and was developed with the support of WIPO and many national and regional patent offices. It is being regularly used by UN agencies and public health institutions as a key source of patent information on HIV medicines. In addition, some national patent offices have improved their on-line patent information databases. Other efforts have also been carried out to identify patents in relation to medicines included in the WHO Model List of Essential Medicines or for other diseases.

At the March 2011 workshop mentioned above, it was also noted that the work undertaken by the European Patent Office (EPO) to facilitate the retrieval/identification of patents relating to climate change technologies was a very useful approach that could potentially be adapted for the health field, e.g. by focusing on certain specific diseases[6] and/or specific active ingredients used in the treatment thereof.

More specifically, the EPO has developed a dedicated classification scheme for patents relating to climate change technologies (Y02, Y04S) which is structured according to the needs of external users, and fully integrated into the EPO's Patent Information services,

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[3] WHO, Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property, Resolution WHA61.21, item 5.1. (c).

[4] See pages 61, 62 and 162 of the study, available at http://www.who.int/entity/phi/implementation/trilateral_cooperation/en/, http://www.wipo.int/globalchallenges/en/health/trilateral_cooperation.html, or http://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm

[5] See the Summary and key points: http://www.who.int/phi/access_medicines_feb2011/en/index.html, http://www.wipo.int//meetings/en/2011/who_wipo_wto_ip_med_ge_11/, http://www.wto.org/english/news_e/news11_e/trip_18feb11_e.htm

[6] Further information on this project is available at: http://www.epo.org/news-issues/issues/classification/classification.html and e-learning module: https://e-courses.epo.org/wbts/y02_en/player.html

facilitating particularly external users' access to climate change relevant patent literature. This aids not only dissemination of relevant technical knowledge through patent publications, but also searches on the extent of patent protection in any one field. Moreover, it allows producing statistics on patenting trends to support policy.

In particular, the EPO vast data collection and examiners' expertise provide a unique comparative advantage in searching relevant chemical active ingredients. The result is a comprehensive range of services relating to relevant patent information, which potential partners can further enrich and analyse according to users' needs.

It was therefore considered appropriate to investigate the feasibility of a similar approach for particular health-related areas.

3. Scope of work

Originally, the final deliverable was thought to be the establishing of a user-friendly, freely accessible information system (e.g. a database or a meta-database) containing patent information related to a number of medicinal (end-) products for a particular range of countries. The system was supposed to allow users to file requests for patent information on specific medical products in specific countries.

The Group wanted to define, describe and establish an integrated 5-step-system based on the expertise of all stakeholders. According to the originally drafted Terms of Reference, the 5 step system should contain the following work streams:

1) Identification of relevant medical products (African Union, WHO, NGOs, health community) and the level of service needed by the users (starting point: the Medicines Patent Pool's Patent Status Database on Selected HIV Medicines).

2) Interpretation/ Categorisation of patents according to product, process and use specifications (e.g. formulations, methods of manufacture, dosages etc.).

3) Identification of relevant patents and patent family members (Patent offices, such as EPO), including those relevant to the product deconstruction, i.e. relevant to generic production.

4) Identification of patent family members in countries of interest to users, and their legal status (WIPO in cooperation with national patent authorities).

5) Dissemination of the data (e.g. via free accessible database, possibly integrated into existing patent information services at IPO (EPO, WIPO or other) websites).

It was planned to create the final deliverable via a pilot project with 10-20 medical products (some suggested fewer) for relevant diseases based on the public health needs. The objective of this pilot project was the initial set-up of the above described information system which

could be further developed and extended to additional medical products based on the user's need.

In November 2012, the group agreed to reduce the scope of the exercise by starting a pilot project. One compound identified by potential users was supposed to be explored in more detail in order to assess issues with regard to feasibility, actual user requirements and necessary resources both initially and for maintenance.

Based on the suggestion by MSF the compound GS7977, a Hepatitis C pipeline drug now largely known as Sofosbuvir, has been chosen for the reduced pilot project.

Following an internal endorsement by EPO, the pilot project with the above mentioned compound has started early May 2013.

4. Pilot project

The initial pilot project saw the EPO undertake initial patent searching and patent classification, and then provide data to a commercial service provider, CambridgeIP, for enhancement of the results (where possible).

The initial pilot confirmed that the EPO could provide relevant patent family[7] information. CambridgeIP could then add information on patent family members in Africa which was not readily available to the EPO. Using commercial methods and tools, CambridgeIP was able to confirm that it could further categorise and analyse the data provided by the EPO, making the resulting dataset more complete and end-user friendly.

Brief outlines of the EPO and CambridgeIP work in this initial pilot are provided below.

4.1. Phase 1: Identification of patents

The EPO expertise relevant to this project relates primarily to the ability of highly skilled examiners to search patent and non-patent literature and identify all relevant patent applications and granted patents; secondly, to classify patent documentation. A team of examiners specialised in chemical structure, formulations, combinations and medical uses was made available to search relevant patents related to compound GS7977 for the treatment of Hepatitis C, with the international non-proprietary name Sofosbuvir. Patent families were manually sorted in a number of pertinent categorises: synthesis, derivative, galenic, combination, indication and dosage. These are explained further in the Annex.

[7] A patent family is a set of either patent applications or publications taken in multiple countries to protect a single invention by a common inventor(s) and then patented in more than one country. A first application is made in one country – the priority – and is then extended to other offices. For further information on patent families please see the EPO guidance: http://www.epo.org/searching/essentials/patent-families/definitions.html

Results delivered by EPO

The research which was performed by using EPO internal as well as external databases produced a list of 169 relevant patent families, including both patent applications and granted patents. It is to be noted that this is a "snapshot" of the situation on a single day. These were manually sorted into the following categories: synthesis (3), derivative (8), galenic (7), indication (11), dosage (8) and combination (146), with some overlapping between the groups. For a more detailed description of these groups see Annex 1. For each "family", the EPO could deliver a list of its members available in the databases (even though the list was not complete), and provide some legal status data on family members.

The use of a number of internal and external databases was considered necessary. Each database search resulted in valuable "hits" not found elsewhere.

This search and manual "classification" of its findings required approximately 6 person-days. Independent but overlapping searches carried out by different examiners produced effectively similar results.

The remaining list of 17 active compounds previously proposed by the WG was superficially investigated for (i) the likely number of hits in a search and (ii) the classification effort required. Sofosbuvir appears to be a younger compound with fewer related patents (less than 200 hits); most compounds would require significantly more effort (between 5,000 and 10,000 hits), some an order of magnitude more. As for a few a manual sorting would not be practical, automated and semi-automated approaches may be required (more than 15,000 hits).

4.2. Phase 2: Categorisation of identified patents

CambridgeIP's expertise in this project is given by the ability of its highly trained patent search, patent data processing and patent analysis experts, together with its ability to recover global patent data including African patent data. For the purposes of this pilot, CambridgeIP constrained its work to patent publications from the Organisation Africaine de la Propriété Intellectuelle (OAPI)[8] and the African Regional Intellectual Property Organization (ARIPO)[9].

For the initial pilot CambridgeIP applied a combination of patent databases[10], including CambridgeIP's proprietary database "DiscoverIP™" and the company's IP Landscape® methodology to augment the EPO's initial data provision. This approach yielded a further 17 patent family members from Africa to be added to the initial EPO dataset, of which were 3

[8] see http://www.oapi.int/

[9] see http://www.aripo.org/

[10] CambridgeIP aggregates patent data from commercial providers and patent offices to ensure industry standard patent data coverage. Patent Databases routinely aggregated by CambridgeIp include: PATSTAT, INPADOC, US PTO, Total Patent (Lexis Nexis), various Thompson Reuters patent data sources and free online patent databases.

ARIPO granted patents, 13 ARIPO patent applications and 1 OAPI granted patent. Out of these additional 17 patent families, 15 had not been cited by EPO, due to different search strategies used.

CambridgeIP undertook semi-automated categorisation of the 17 new patent family members, based on patent claims, with expert review for quality control purposes. The categorisation exercise resulted as follows: synthesis (4), active principle ingredient and derivatives (14), galenics (2), indication (11), combinations (6), dosage (0), with some overlapping between the groups[11].

Findings delivered by CambridgeIP

For each patent publication cited, CambridgeIP delivered a list of simple and extended family members[12]. It could also provide the legal status of the most active jurisdictions[13]. Moreover, further analysis by CambridgeIP could identify top patent owners[14] and most important patent families[15] as well as determine whether or not patents remain in force in the focus countries[16].

To confirm its results, CambridgeIP undertook a brief market and technology intelligence analysis confirming that the drug was developed by Pharmasset and acquired by Gilead. The results were in line with the successive patent assignments observed by CambridgeIP and correspond to the information on CambridgeIP's clinical trials database, showing Gilead clinical trials on Sofosbuvir.

[11] For further details on the categorisation deliverable see the excel sheet 'AfricaPlatformAccess' document in Annex 2 or at http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform-africa/index_en.htm

[12] Further information on patent family available in the EPO guidance: http://www.epo.org/searching/essentials/patent-families/definitions.html. To be mentioned, definitions 1 and 3, describing respectively the simple patent family and the INPADOC patent family'. It should be noted that CambridgeIP includes jurisdictions in 'extended' family coverage not included in the INPADOC data, but following the INPADOC definitional guidance.

[13] Statistics in relation to *relevant* patent activity will be derived from the identification and categorisation of patents undertaken in the course of the project.

[14] Most prolific owners of *relevant* patents in each category will be identified based on the aggregation of the data and categorisation parameters imposed at the outset of the project.

[15] A range of indicators of importance will be deployed. Potential indicators of importance include the number of relevant members in a patent family, the count of patent citations relating to a patent family and the legal and fee status of various patent family members (e.g. is a patent granted, is the patent maintained or abandoned).

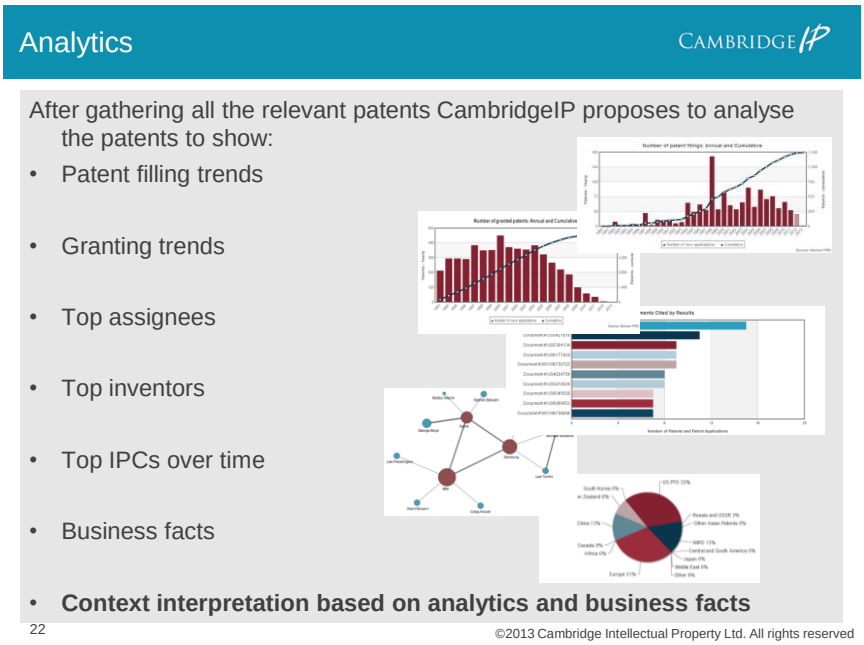
[16] Focus countries will be defined at the outset of the project.

4.3. Conclusions

The combination of EPO and CambridgeIP data results in a more comprehensive set of information than the one that could be provided by both parties singularly.

- The EPO is able to provide valuable patent data from its extensive patent resources, and to undertake categorisations using the expertise of its patent examiners.
- CambridgeIP is able to augment EPO data and make additional categorisations using both its commercial databases and tools, and the expertise of its patent consultants.

Graphical information on trends, top patent owners and patent coverage can make the 'dense' patent landscape easier to navigate



CambridgeIP and the EPO now need to assess the scope of a project to undertake similar search and analysis across the remaining focus compounds.

- This initial pilot has provided valuable information, and the EPO and CambridgeIP are confident that they can classify the remaining compounds by level of difficulty to better assess the amount of work that would be required.

Once the exercise has been completed, an automated alert could provide on-going information to end users.

- CambridgeIP proposes to establish MonitorIP, a service that will alert a database manager of any updates to patent information in a particular area. MonitorIP is a software based service that can be optimised with an expert quality control and categorisation review. Even though the cost of such a service will depend on the level

of expert review needed, it will in any case reduce considerably the amount of human input needed to update the database.

- The MonitorIP service could be included as part of the project (to keep project information up to date over a period of time - e.g. 2 years), or could be a separate offering once the project has been completed (to update the patent information delivered by the project periodically – e.g. every year).

The EPO and CambridgeIP further wish to engage with potential end-users to comprehend in more detail their requirements.

4.4. SWOT analysis

Strengths

- The pilot provided more detailed information on the feasibility of this proposal and the resources required.

- The pilot's outcome represents an initial patent information product in the form of a more structured patent documentation collection on Sofosbuvir for countries for which data are available (patent search and categorisation). Based on the pilot project further evaluation of the results with intermediate and end users (e.g. MSF, WHO, UNITAID) can be carried out.

Weaknesses

- Limitations of data coverage especially concerning countries of interest. Applications are not always published. Also, EPO did not have data covering all family members. This was shown by those found by CambridgeIP, for which no data was available in Espacenet.

- Limitations of legal status information, which is considerably more limited than family information.

- To date, the feedback from potential users given is too limited to allow information providers (EPO, IP Cambridge) to define how useful results are, and to determine the requirements for a future service.

- Categorisation of patents in EPO is manual, hence, resource-consuming. Initial assessments indicate that overall, resources required may be 200-300 examiner days to search and classify most of the proposed substances, with a few requiring an impractical level of days for manual classification. With the finer classification now proposed, this could increase to 450 examiner days total. Automatic categorisation must be considered for these few, with an expected much lower quality of categorisation. Limitation of the search to documents in which the active agents

appear only in the claims (and eventually the examples) could be an option to reduce the number of "hits".

- Initial feedback from WHO (P. Beyer) has indicated that more manual filtering would help considerably to identify the most important patent families, which could then again be more critically analysed for their actual scope of protection.

- Search and categorisation will also require a periodic update due to continual publication of new data and data obsolescence. This maintenance will also require manual resources within the EPO.

Opportunities

- CambridgeIP offers a good coverage for the ARIPO publications and granted applications, as well as for OAPI granted applications.

- CambridgeIP's proprietary methodology provides a combination of automatic categorisation for easy topics using various IT tools, complemented by manual categorisation to complete the classification of difficult patent subsets. CambridgeIP methods and categorisation decision support tools (RedEyeTM) should assist categorisation efficiency and quality control in future exercises.

- CambridgeIP can provide periodic updates with their MonitorIP™ service that can be completed by an expert quality control, allowing the maintenance of the platform with minimum resource.

Threats

- The main threat is the level of resources required for the manual sorting.

- Data evolution over time. Any list of data or patent information product risk leading to wrongful analysis and patent landscaping if data is not updated regularly. Lack of fund and limited resource may cause a failure to update data.

  CambridgeIP does not currently provide data for OAPI pending patent applications (i.e. not granted or pending OAPI patents).

5. Final recommendations

Based on the analysis above, the Working Group on Patent Information recommends the following:

1. A detailed evaluation of the pilot results by potential users (e.g. MSF, WHO, UNITAID, MPP[17]) is required to help refine the actual user requirements. User types already identified include patent data 'producers' such as EPO and WIPO, data 'intermediaries' such as MSF, WHO and UNITAID, and a wide range of 'end users' of data and analysis such as corporations, public procurers, academic researchers and think tanks. Importantly, these users may include enterprises that will take the initial results, and process them further e.g. to produce landscape reports, or include them in their own databases.

   The users listed above were asked to complete "Annex 2", to help guide the feedback. This feedback is still "in progress"; however, EPO has completed a **draft** version on the basis of emails and discussions to date primarily with WHO and MPP.

   The users have indicated that a finer classification is required, as detailed in Annex 3. In addition, this improved classification should include search results from a refined search based on the authorised or potentially authorised delivery of the drug, e.g. Sofosbuvir 400mg delivered in a solid oral form in combination with ribavirin (respectively peginterferon and ribavirin). Initial estimates indicate that this refined classification would require 20-50% additional resources for the EPO and CambridgeIP.

2. Due to the importance of the issues remaining, including the feasibility of such an approach with more mature drugs involving considerably more patent families, it is recommended to i) refine the Sofosbuvir results as in 1) above, and ii) move to a second level of pilot including up to 6 compounds (1-2 more straightforward, 2 intermediate and 2 compounds involving very large numbers of compounds). This is considered necessary before committing to an initiative involving up to 20 active ingredients.

3. An initial assessment should be made concerning the potential number of active ingredients that might finally be required, and the breadth of countries. The final list might stretch to 100 countries (to be confirmed). It was initially indicated that the original list of 17 active ingredients was in itself considered a pilot. If the final list of active ingredients, and / or the final list of interesting countries were to be much larger, both of these factors might influence the approach from the start.

[17] MPP are not involved in HCV as such; they are however interested in similar results for other active ingredients, and are therefore giving feedback on the pilot results.

4. If a claim analysis is required, and if those patents that are finally identified as the most relevant would need to be explained in terms understandable to non-experts (as suggested by WHO), both of these initiatives would have to be conducted by an independent body (i.e. not a patent office) and would also require considerable resources.

5. Partners would need to be found both for the required skills and for funding expert resources and data access requirements to deliver on recommendations 1-4.

6. It is possible that the patent (application) holders themselves, presumably the pharmaceutical enterprises, could relatively easily deliver comprehensive family and legal status data for each relevant patent family. The acquisition of this information from individual patent offices world-wide could be very resource intensive, time consuming and perhaps not too successful.

7. In making the assessments outlined in the final recommendations above, the Group will continue consultation with WIPO and will explore in close cooperation with WIPO and other potential information suppliers possible specific contributions to the project.

6. List of Annexes

6.1 Mapping exercise

6.2 EPO Classification procedure

6.3 Feedback required from potential future system users

6.4 Finer classification of Sofosbuvir search results, including results from finer searches around potentially authorised deliveries of Sofosbuvir

6.5 How to use EPO results

Annex 1

Mapping exercise

According to the Terms of Reference, the Project Group also carried out a mapping exercise and collected information on existing initiatives in this field.

- **Medicines Patent Pool database**
  http://www.medicinespatentpool.org/patent-data/

  Since its founding in July 2010, the Pool has been collaborating with national patent offices around the world through the World Intellectual Property Organization to collect data on which HIV medicines, formulations and combinations are patented, and where.

  The Pool's Patent Status Database is currently the most complete single source of open access information about critical public health related patents in developing countries. The Pool launched the public access database on 4 April 2011 in the hopes that others could benefit from the work that had been done, and also contribute by providing additional information, making the database more complete. Currently, the database enables access to information on the patent status of 25 antiretroviral medicines in about 80 countries.

- **WIPO Patent Landscapes**

  http://www.wipo.int/patentscope/en/programs/patent_landscapes/published_reports.html
  Patent landscape reports on various topics have been published by international organizations, national intellectual property offices, non-governmental organizations and private sector entities. WIPO has compiled a list of such reports that are freely available or can be obtained upon request, either free of charge or for a fee.

  http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/
  WIPO has been mandated to prepare patent landscape reports in areas of particular interest to developing and least developed countries, such as public health, food security, climate change and environment. For that purpose, WIPO is developing in cooperation with interested external partners, such as institutions from member States, intergovernmental or non-governmental organizations, the scope of each report. The author of each report is selected in a tendering process. Of particular interest are the completed landscapes on:

  - Ritonavir:
    http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/ritonavir.html
  - Atazanavir:
    http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/atazanavir.html
  - Vaccines for selected diseases:
    http://www.wipo.int/patentscope/en/programs/patent_landscapes/reports/vaccines.html
  - Ongoing project on selected neglected diseases.

- **WIPO's Global Challenges program**

  http://www.wipo.int/globalchallenges/en/
  Scientific and technological innovation has contributed to significant advances in treating health conditions. The challenge for public health policymakers is to provide the necessary incentives for innovation in this area and to promote access to health innovation, particularly where its benefits are most urgently needed. WIPO's Global Challenges program seeks to raise awareness and understanding of the interplay between innovation, technology transfer and diffusion, in particular the complexities underlying health innovation and access to medicines.

- **WIPO Re: Search**

  http://www.wipo.int/research/en/
  WIPO launched WIPO Re: Search, a new consortium where public and private sector organizations share valuable intellectual property (IP) and expertise with the global health research community to promote development of new drugs, vaccines, and diagnostics to treat neglected tropical diseases, malaria, and tuberculosis. These diseases negatively affect the lives of more than one billion people, many of whom live in the world's least developed countries. WIPO Re: Search aims to stimulate more research and development for new and better treatment options for those suffering from these conditions.

  It provides access to intellectual property for pharmaceutical compounds, technologies, and – most importantly – know-how and data available for research and development for diseases. By providing a searchable public database of available intellectual property assets and resources, WIPO Re: Search facilitates new partnerships to support organisations that conduct research on treatments for neglected tropical diseases, ultimately improving the lives of those most in need.

  An important aspect of WIPO Re: Search is the opportunity it creates to transfer knowledge and build capacity at institutional and individual, human level. Recognizing the essential human aspect of development, IP Australia, the Australian Government agency that administers intellectual property (IP) rights, has generously made available financial resources under a Funds-in-Trust grant to WIPO to enable scientists from developing and Least Developed Countries to take 'sabbaticals' at the research facilities of developed country Members of WIPO Re: Search. Placements for these 'hosting arrangements' are arranged by BIO Ventures for Global Health, and to date have involved scientists from Cameroon, Egypt, Ghana, Nigeria, and South Africa.

- **WHO, WIPO, WTO Trilateral Cooperation on Public Health, Intellectual Property and Trade**

  http://www.who.int/phi/implementation/trilateral_cooperation/en/

  http://www.wipo.int/globalchallenges/en/health/trilateral_cooperation.html

  http://www.wto.org/english/tratop_e/trips_e/who_wipo_wto_e.htm

  The World Health Organization (WHO), the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) are strengthening their cooperation and practical coordination at the working level on issues around public health, intellectual property and trade towards the broader context of the WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), the WIPO Development Agenda and the WTO Declaration on the TRIPS agreement and public health.

  The three organizations meet regularly, exchange information on their respective work programs and discuss and plan, within the possibilities of their respective mandates and budgets, common activities. The trilateral cooperation is intended to contribute to enhancing the empirical and factual information basis for policy makers and supporting them in addressing public health in relation to intellectual property and trade.

Annex 2

EPO Classification procedure

The following categories were anticipated for data structure:

Synthesis:	aspects of chemical synthesis (including intermediates)
Derivatives:	chemical entity aspects (e.g. salts, polymorphs, conjugates)
Galenic:	formulation aspects (other than mere combination therapy)
Combination:	aspects of combination therapy
Indication:	aspects of further therapeutic indication (i.e. beyond principal indication in basic patent)
List:	mention of compound in list **in description** without specific preference
Noise:	no specific pertinence to drug Sofosbuvir (including mere background or comparison)
Personal:	collection of documents for further consideration in classification procedure

Note concerning "Combinations":

The group "Combinations" above lists all 146 patents citing combinations with Sofosbuvir. If however the 116 "List" results are subtracted from these, the resulting 30 hits reveal the most relevant "Combinations".

The full EPO and CambridgeIP search results are available at:

http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corporate_responsibility/platform-africa/index_en.htm

Each patent number in the first tab represents a family of patents with (1– n) family members. These may be viewed in EPO Espacenet (www.espacenet.com). "INPADOC family" and CambridgeIP results are displayed in the last tab.

Annex 3

Feedback required from potential future system users

The following information is required to help define the user requirements of future services. The EPO and CambridgeIP have invested significant resources to indicate services that might be developed. Feedback is now urgently required on what potential users actually wish to achieve, and how the pilot results developed could or could not support the users' goals.

Please identify the organisation and contact details:

1. Brief summary of users' goals: There are two main categories of users: (i) intermediate users, who exploit the data produced by information suppliers (EPO, IP Cambridge or others) to feed databases or any other type of information platform (e.g. MPP); (ii) end-users (e.g. MSF), who exploit the patent information, either as provided by information suppliers or in a version enhanced by intermediate users, for the purposes of facilitating access to medicines (e.g. procurement).

Please provide a brief explanation (half- to one page) of what you would like to achieve, in high level terms:

EPO summary of discussions to date:

i) to use the most relevant patent families as the basis for finer analyses for landscaping reports;

ii) for those patents most relevant (in particular relevant to the authorised forms), to include these in a database with maximum possible family member and legal status information;

iii) to use the most relevant patent families for detailed claims analyses to indicate specific relevant patent protection in specific geographical regions.

2. Brief summary of final online service to be provided, and of typical users' steps envisaged to achieve the desired result.

Please provide a brief explanation (half-page) of service to be provided:

Typical steps:

1. *Step:* *Result:*
2. *Step:* *Result:*
3. *Step:* *Result:*
4. *Step:* *Result:*

EPO summary of discussions to date: See 1. Above

3. Do you consider yourself and/or your organisation to be the end users of this potential service, or would you use and adapt this information to provide further products or services?

Please provide a brief explanation of further products or services (half-page):

EPO summary of discussions to date:

Mostly, other information suppliers or intermediate users would use the EPO/ Cambridge IP results as a starting point for a more detailed analysis.

4. What information already provided by EPO and CambridgeIP (potentially also to be proposed by WIPO) would you use, and in what way? What would you like to see in addition?

Please provide a brief explanation:

EPO summary of discussions to date:

The patent families found were relevant, but an improved classification would help. A proposed finer classification is given in Annex 3. In addition, one or more finer searches per compound should be conducted based on the (potential) authorised use of the active compound. Again, an example is given in Annex 3.

5. Final scope:

    a. The existing list to be considered contains 17 compounds. However, once a service is successful, there are often requests to extend it. The overall approach taken could very much depend on the intended final product. Could you please identify what you would consider to be the extend of the service in terms of the diseases and active ingredients to be included, specifically:

        i. short term priorities : (i.e. in the first stage and year);

        ii. mid-term : (i.e. in subsequent 2-3 years);

        iii. final scope : (i.e. after 5-7 years).

EPO summary of discussions to date: short term 6 compounds, next stage 10 compounds, final scope approximately 25 compounds in total, with two to three compounds added per year.

    b. Likewise, could you please indicate which countries/ states / regions you would like to see included:

        i. short term priorities: (i.e. in the first stage and year);

ii. mid-term: (i.e. in subsequent 2-3 years);

iii. final scope: (i.e. after 5-7 years).

EPO summary of discussions to date:

i) Those family members contained in EPO and CambridgeIP databases could be easily found.

ii) Applicants could relatively easily provide family and legal status data

iii) Finally, some organisations would want family and legal status data for up to 100 countries. Without applicant data, this would be very difficult to complete.

Annex 4

Finer classification of Sofosbuvir search results, including results from finer searches around potentially authorised deliveries of Sofosbuvir

The EPO and CambridgeIP have conducted a search and classification exercise to find the patent families most relevant to Sofosbuvir.

Feedback from WHO and MPP[18] has indicated that, although the EPO and CambridgeIP results could be useful, the number of patents in each classified area is still large, and this would require considerable further analysis by potential users of the results to find the most relevant patent families.

After further discussions between WHO, EPO and CambridgeIP, including discussion on the feedback from MPP, the conclusions are the following:

1. The EPO, with assistance from CambridgeIP, could classify the documents more finely. A refined classification might compose:
    a. Synthesis – no finer divisions
    b. Formulations/Galenic –
        i. HCV-relevant
        ii. those individualising Sofosbuvir *vs*
        iii. those more generic
        iv. (above could also be a 2x2 division, giving 4 sub-classes)
    c. Combinations –
        i. Sofosbuvir generally included in description
        ii. Sofosbuvir included in claims
        iii. Specifically mentioning treatment of HCV vs. more general anti-viral
        iv. (above could also 2 x 2 division)

[18] MPP are not involved in HCV as such; they are however interested in similar results for other active ingredients, and are therefore giving feedback on the pilot results.

d. Indications

    i. Those relevant to HCV

    ii. Other groups, mentioning indication ...for disease 1

    iii. ...for disease 2

    iv. ...for disease 3

    v. ...for disease “n”

e. Dosage - effectively a sub-class of indication and formulation/galenic, therefore

    i. Dosages relevant for specific indications

    ii. Dosages relevant for certain formulations ...

f. See 3. Below - “**Particular authorised Sofosbuvir deliveries**...”

    i. Sofosbuvir 400mg delivered in a solid oral form in combination with ribavirin, Sofosbuvir 400mg delivered in a solid oral form in combination with peginterferon and ribavirin.

Annex 5

How to use EPO results

The following is an example of how to use the EPO results within the EPO's Patent Information services, which are readily available free of charge via the internet. The following is only a brief summary of some of the services available. For a more comprehensive summary, please refer to the Help and handbooks provided.

1. The EPO results in the Excel spreadsheet (first tab) represent **the most relevant patent families** found when searching for Sofosbuvir and its most closely related substances. These have been classified manually into the above-mentioned groups.

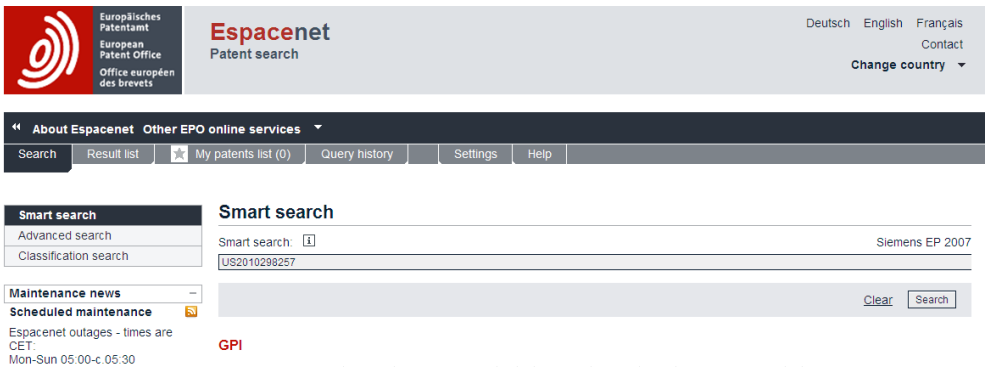
Data provided by EPO

Project title *Platform on Access to Medicines in Developing Countries with a Focus on Afri*

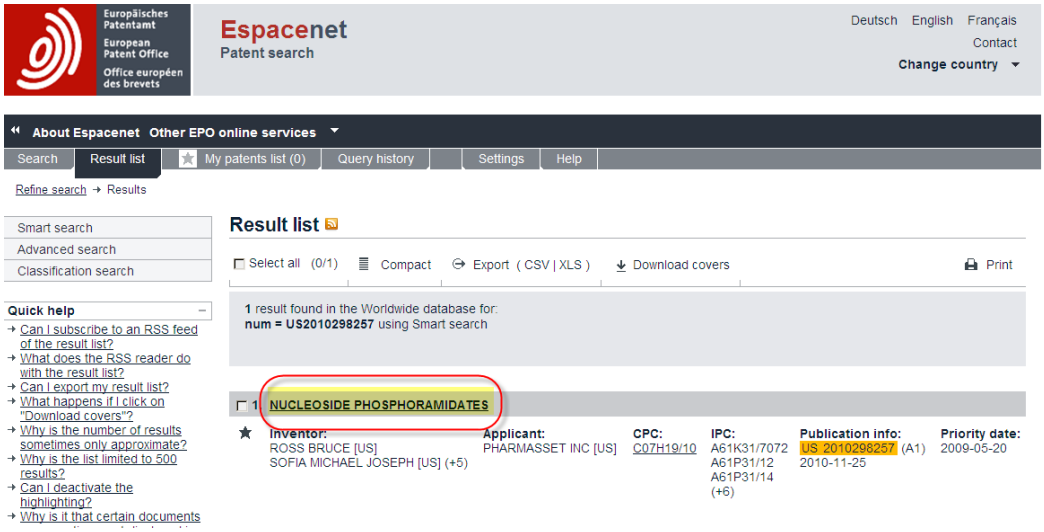
Total (viewer-fam)	synthesis	derivative	galenic	combination	indication	dosage	list	noise
169	3	8	7	146	11	8	116	1
US2013109647	WO2012012465	WO2012129112	WO2013024158	US2013109647	EP2583677	US2013109647	WO2013067267	US2012220562
WO2013064538	US2010298257	WO2012107579	WO2013056132	WO2013064538	WO2012130862	EP2583680	WO2013064538	WO2012040923
WO2013067267	WO2008121634	US2011245484	WO2012139028	WO2013067267	WO2012118712	WO2013000855	WO2013063462	US2011268795
WO2013063462		US2011251152	WO2012118712	WO2013063462	WO2012072655	WO2012130862	WO2013061052	WO2011089166
WO2013059278		US2010298257	WO2012050850	WO2013059278	US2012107278	WO2012072655	WO2013059278	DE102009028015
WO2013061052		WO2008121634	WO2011156578	WO2013049352	WO2012045704	US2012107278	US2013102589	US2010317568
WO2013049352		RU2009139968	WO2013061052	WO2013056046	WO2012031763	WO2012045704	WO2013056046	US2011092415
WO2013056046		AU2012241173		US2013102589	WO2012011917	US2011306541	WO2013055563	US2011207699
US2013102589				EP2583677	TW201215604		WO2013049407	AU2012247053
EP2583677				US2013102525	WO2012003030		WO2013049352	US2011257121
US2013102525				EP2583680	US2011306541		WO2013045658	EP0343545
EP2583680				US2013102558			WO2013045668	US5086122
US2013102558				WO2013055563			US2013078214	
WO2013055563				WO2013049407			US2013078217	
WO2013056132				WO2013045658			WO2013039878	
WO2013049407				US2013078217			WO2013039876	
WO2013045658				WO2013045668			WO2013036994	
US2013078217				US2013072528			US2013064794	
WO2013045668				WO2013045460			US2013064793	
US2013072528				US2013078214			WO2013026163	
WO2013045460				WO2013039876			WO2013026162	
US2013078214				WO2013039878			WO2013025992	
WO2013039876				WO2013040492			WO2013025975	
WO2013039878				WO2013036994			WO2013017653	
WO2013040492				US2013064793			WO2013016499	
WO2013036994				US2013064794			WO2013016490	
US2013064793				WO2013033901			WO2013013009	
US2013064794				WO2013033899			WO2013010112	
WO2013033901				WO2013033900			WO2013009737	
WO2013033899				WO2013028953			WO2013009735	
WO2013033900				WO2013024158			WO2012173983	
WO2013028953				WO2013025992			US2012302538	
WO2013024158				WO2013025975			WO2012154777	
WO2013025992				WO2013024155			WO2012151195	
WO2013025975				WO2013026162			WO2012142093	
WO2013024155				WO2013026163			WO2012142085	

Therefore, under "Synthesis", the result US2010298257 represents a patent family.

2. Using the EPO's Patent Information services, go to: www.espacenet.com – "Open Espacenet at the EPO" – [Enter patent number such as US2010298257, "Search"]:



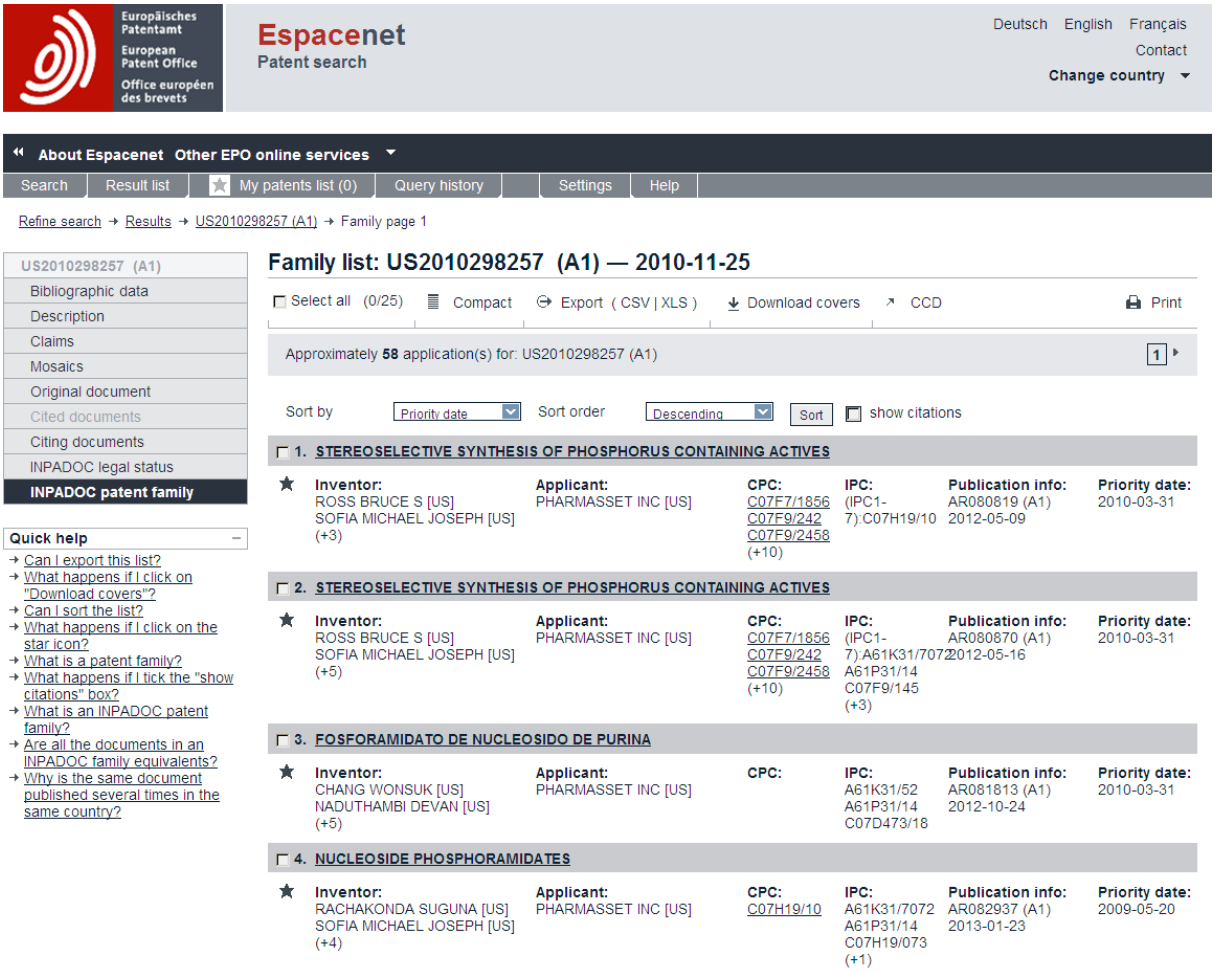
3. The results screen shows the desired patent (application) – click on the patent (application) found, shown by the red outline:



4. The resulting patent (application) details are given:

5. Use the menu to access, amongst others i) Original document, ii) INPADOC legal status (actual status of patent or application) iii) INPADOC patent family to find all the states in which this patent or application has been filed. Please note that, although the EPO databases contain some 88 million patent documents, many family members will still not be found.

6. Example of services: List of family members:



Each one of the 58 patents/ applications listed is linked to the original document through one or more common priority documents; typically, but not always, these documents will be identical in their technical content.

For each one of these family members, the documents themselves and further information relating to legal status, citations and further family members may also be retrieved.