Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
Identification of US-pharmaceutical patents expiring between 2018 and 2022 and their effect on the Brazilian domestic market

Thalita D.M. Paes, Lucas F. Aguiar, Tatiana D. Martins

**Abstract**

This work presents the status, in Brazil, of pharmaceutical patents granted by US Patent and Trademark Office (USPTO) and their role on the Brazilian Pharmaceutical market. Data show that 27.1% of the US-granted patents filed in Brazil are granted by Instituto Nacional da Propriedade Industrial (INPI) and 76.5% of them have their term extended due to provision of article 40 of the Brazilian Industrial Property Law (LPI 9279/96), while 65% of these US-patents are not valid in Brazil, evidencing market openness and independence of patent examination of INPI before USPTO. The effects of INPI backlog of patent examination on pharmaceutical market are also highlighted. These aspects are relevant to establish better strategies to reduce backlog and to orient public policies to stimulate the Brazilian industry, especially with respect to the production of generic and similar drugs.

**Keywords:** Pharmaceutical patents, Brazilian industrial property law, Patent backlog, Patent term extension, RStudio

**1. Introduction**

Prior to 1945, pharmaceutical compounds and processes were patentable in Brazil, under the Law of August 28th, 1830; Law 3129 of October 14th, 1882; Decree-Law 24,507 of June 29th, 1934 and the Political Constitution of the Empire of Brazil, enacted on March 25th, 1824; until the enactment of Decree-Law 7903 of August 27th, 1945, and Decree 1005 of October 21st, 1969, which excluded pharmaceutical compounds and processes, respectively, and were reinforced by Law 5772 of December 21st, 1971, which was in force until Brazil adheres to Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS)

The current Brazilian industrial property law, LPI 9279/96 was enacted right after Brazil’s adhesion to TRIPS, and immediately complied with its requirement of non-discrimination between distinct fields of technology in the members’ patent regimes, and products and processes that were not patentable by the previous Brazilian law in force (Law no 5772/1971), became patentable.

Brazil could benefit from a period up to 10 years to adapt its legislation to TRIPS, since the International Agreement, in its articles 65.2 and 65.4 provided that developing countries could postpone the date of application of the provisions of the Agreement for a period of 4 years in addition to the period of 1 year after the World Trade Organization Constitutive Agreement came into force. Also, the obligation to patent protection of products of technological sectors that were not patentable in their territory for an additional period of 5 years. Therefore, Brazil waived these rights to prompt adaptation of the Brazilian Industrial Property Law to TRIPS, due to international pressure, such as the threat of being included in the Priority Watch List (annually updated and available at: https://ustr.gov/about-us/policy-offices/press-office/press-releases/2019/april/ustr-releases-annual-special-301), a list of countries whose intellectual property protection was inadequate for international trade relations, which is reported by the Office of the United States Trade Representative (USTR). It also yielded to internal pressure of patent owners to update their patent documents and confer them longer terms, with legislation change, since the law in force, law 5772/71, advocated a 15-year term for invention patents, while TRIPS conferred 20-year term for invention patents.

Nevertheless, LPI 9279/96 was never a consensus because, at one side, patent owners pushed for immediate harmonization of legislation, defending that it would be an important instrument to stimulate innovation in Brazilian industry; at the other side, national industries, yet technologically back warded and dependent of products that were merely copies of foreign patented products, advocating the period of harmonization predicted by TRIPS would be essential for the industry adaptation to the changes. In fact, by 1996, Brazil had already fully adhered to TRIPS and the impact was instantaneous, due to the rushed legislation harmonization. This prompt adherence of Brazil to TRIPS could benefit from a period up to 10 years to adapt its legislation to TRIPS, since the International Agreement, in its articles 65.2 and 65.4 provided that developing countries could postpone the date of application of the provisions of the Agreement for a period of 4 years in addition to the period of 1 year after the World Trade Organization Constitutive Agreement came into force. Also, the obligation to patent protection of products of technological sectors that were not patentable in their territory for an additional period of 5 years. Therefore, Brazil waived these rights to prompt adaptation of the Brazilian Industrial Property Law to TRIPS, due to international pressure, such as the threat of being included in the Priority Watch List (annually updated and available at: https://ustr.gov/about-us/policy-offices/press-office/press-releases/2019/april/ustr-releases-annual-special-301), a list of countries whose intellectual property protection was inadequate for international trade relations, which is reported by the Office of the United States Trade Representative (USTR). It also yielded to internal pressure of patent owners to update their patent documents and confer them longer terms, with legislation change, since the law in force, law 5772/71, advocated a 15-year term for invention patents, while TRIPS conferred 20-year term for invention patents.

**E-mail addresses:** Thalita.paes@patentabilit.com.br (T.D.M. Paes), tatiana@ufg.br, tati.duque@gmail.com (T.D. Martins).

https://doi.org/10.1016/j.wpi.2020.101999

Received 30 August 2019; Received in revised form 10 July 2020; Accepted 25 September 2020

Available online 6 October 2020

0172-2190/© 2020 Elsevier Ltd. All rights reserved.
instantly affected the Brazilian Patent Office, Instituto Nacional da Propriedade Industrial (INPI) operation [7–9], since pharmaceutical products had not been patentable from 1971 to 1996, the Patent Office lacked enough documents and examination guidelines in these fields of knowledge to analyze these matters, which contributed to create a backlog on patent analysis that was not overwhelmed the Office until now [10,11], causing an average exam delay time of 13 years [12].

In addition, the transitional articles of the current patent law 9279/96 instituted the mailbox and pipeline patents, and provided the prior consent of the Agência Nacional de Vigilância Sanitária (ANVISA - Brazilian Health Surveillance Agency), created in 1999 by Law nº 9,782, of January 26th, 1999 [13], to register medicaments in Brazil and to give prior approval or not to patent applications.

To compensate industries for such examination delays [13], art. 40 of Law 9279/96, in its single paragraph states that, although a patent is valid for 20 years (for inventions, and 15 years for utility models) from the filing date, its minimum term must be 10 years after granted (and 7 years in the case of utility models) by a TRIPS-plus [4,6] provision. Therefore, it is a mechanism to indemnify patent owners for any missed opportunity of valuation or negotiation of patents due to administrative delay, with the collateral effect of extending the market exclusivity for a longer time and instantly affected the pharmaceutical market share in Brazil.

However, this scenario discouraged Brazilian pharmaceutical industries to invest on research and development, since they fail to perform advanced industrial property management, although pharmaceutical field is dominated by technological intensity [13–16], becoming focused on generic and similar drugs production, as a result of an unbalance of Brazilian industry profile, comparing to international industries, reinforced by the impact of the backlog [17]. Due to that evolution of events, the Brazilian pharmaceutical market share, therefore, is dominated by a national industry that is essentially generic producer and subsidiary industries in Brazil that import technological developments from their foreign parent companies, discrepancies that were reinforced by a hushed law implementation.

Patent examination backlog are problematic worldwide. Nevertheless, their reasons can be distinct. For instance, in his work, Rodriguez [18] shows that European Patent Office (EPO) deals with an increasing backlog that is mainly due to a great increase of international patent filings at EPO and they discuss how the office developed strategies to fill the backlog, its minimum term must be 10 years after granted (and 7 years in the case of utility models) by a TRIPS-plus [4,6] provision. Therefore, it is a mechanism to indemnify patent owners for any missed opportunity of valuation or negotiation of patents due to administrative delay, with the collateral effect of extending the market exclusivity for a longer time and instantly affected the pharmaceutical market share in Brazil.

From the retrieved data and their statistical analysis, the status of each corresponding patent in Brazil was obtained to infer on the effects on market of the differences in examinations between both countries, leading to opportunities related to US-patents that lost (or never had) their effect in Brazil, which can be greatly influenced by INPI’s backlog patent examination. This study was performed by using the specialized platform Drug Patent Watch, developed by Yali Friedman PhD, to retrieve documents filed in US. It is a web-based platform that provides information on FDA approved pharmaceutical drugs and their related patents. It provides a fully integrated database of drug patents and offers freeform searching and dynamic browsing, of all types of data pertaining to market freedom to market - [20–23].

Nevertheless, there are legal and procedural provisions of the Brazilian legislation to mitigate such effects, such as:

(i) the fact that it does not constitute infringement of law the previous exploitation of the object of a particular patent application (art. 45 of Law 9279/96);

(ii) the possibility of any interested party to present subsidies (opposition) to the examination that is still occurring (art. 31 of the Law 9279/96) or to plead the invalidity of a granted patent, both in the administrative and judicial scope (arts. 50 to 57 of the Law 9279/96);

(iii) the fact that pharmaceutical patent applications with public health effects are subject to prior consent of ANVISA (art. 229-C of Law 9279/96) and are subject to compulsory licensing (arts.68 to 74 of Law 9279/96);

(iv) the fact that unauthorized third parties may perform acts related to the patent protected invention solely to prepare themselves for a future open market (Bolar provision) with a patent expiration (art. 43 of Law 9279/96) and

(v) INPI promotes priority examinations to pharmaceutical patents related to matters of interest to the Brazilian public health system (Resolution INPI 80 of March 19th, 2013 as amended by INPI Resolution 217 of May 3rd, 2018 and by INPI Resolution INPI PR 239 of July 4th, 2019) [24].

In addition, INPI has recently issued regulations to accelerate the examination flow of patent applications filed up until December 31st, 2016 to eliminate backlog. Resolution 241 of July 2019 [25] provides that foreign applications filed in Brazil and already having a prior art search by any other country will provide patentability manifestation in accordance with such prior art search within 90 days, to sustain a decision of INPI to grant a patent. With this, INPI expect to end backlog in two years [26]. Also, since March 26th, 2020, due to the COVID-19 emergency, INPI had implemented a priority exam, regulated by Resolution INPI PR 239 of July 4th, 2019 [24] focusing on the priority processing of patent applications related technologies to fight COVID-19. This priority procedure will be effective until July 30th, 2021, and it is expected to reduce the time needed to achieve a decision on the patent application. INPI also expect that this action will also stimulate the development of new technologies in this field.

It is crucial to find mechanisms to foster industrial property protection as a way to strengthen Brazilian economy and industry. In this context, considering the Brazilian pharmaceutical market share, patents that feed it, and the interest of the international pharmaceutical industry in domestic market, this work aimed to analyze pharmaceutical patents granted in United States of America (USA), which are considered of high relevance, since they deal with medicines and related products commercialized in USA, and also important to the Brazilian market share, i.e., they are able to influence the Brazilian market share by being impeding to Brazilian industries to produce a medicine, for instance.

2. Methodological background

From the retrieved data and their statistical analysis, the status of each corresponding patent in Brazil was obtained to infer on the effects on market of the differences in examinations between both countries, leading to opportunities related to US-patents that lost (or never had) their effect in Brazil, which can be greatly influenced by INPI’s backlog patent examination. This study was performed by using the specialized platform Drug Patent Watch, developed by Yali Friedman PhD, to retrieve documents filed in US. It is a web-based platform that provides information on FDA approved pharmaceutical drugs and their related patents. It provides a fully integrated database of drug patents and offers freeform searching and dynamic browsing, of all types of data pertaining to market freedom to market - [20–23].

Nevertheless, there are legal and procedural provisions of the Brazilian legislation to mitigate such effects, such as:

(i) the fact that it does not constitute infringement of law the previous exploitation of the object of a particular patent application (art. 45 of Law 9279/96);

(ii) the possibility of any interested party to present subsidies (opposition) to the examination that is still occurring (art. 31 of the Law 9279/96) or to plead the invalidity of a granted patent, both in the administrative and judicial scope (arts. 50 to 57 of the Law 9279/96);

(iii) the fact that pharmaceutical patent applications with public health effects are subject to prior consent of ANVISA (art. 229-C of Law 9279/96) and are subject to compulsory licensing (arts.68 to 74 of Law 9279/96);

(iv) the fact that unauthorized third parties may perform acts related to the patent protected invention solely to prepare themselves for a future open market (Bolar provision) with a patent expiration (art. 43 of Law 9279/96) and

(v) INPI promotes priority examinations to pharmaceutical patents related to matters of interest to the Brazilian public health system (Resolution INPI 80 of March 19th, 2013 as amended by INPI Resolution 217 of May 3rd, 2018 and by INPI Resolution INPI PR 239 of July 4th, 2019) [24].

In addition, INPI has recently issued regulations to accelerate the examination flow of patent applications filed up until December 31st, 2016 to eliminate backlog. Resolution 241 of July 2019 [25] provides that foreign applications filed in Brazil and already having a prior art search by any other country will provide patentability manifestation in accordance with such prior art search within 90 days, to sustain a decision of INPI to grant a patent. With this, INPI expect to end backlog in two years [26]. Also, since March 26th, 2020, due to the COVID-19 emergency, INPI had implemented a priority exam, regulated by Resolution INPI PR 239 of July 4th, 2019 [24] focusing on the priority processing of patent applications related technologies to fight COVID-19. This priority procedure will be effective until July 30th, 2021, and it is expected to reduce the time needed to achieve a decision on the patent application. INPI also expect that this action will also stimulate the development of new technologies in this field.

It is crucial to find mechanisms to foster industrial property protection as a way to strengthen Brazilian economy and industry. In this context, considering the Brazilian pharmaceutical market share, patents that feed it, and the interest of the international pharmaceutical industry in domestic market, this work aimed to analyze pharmaceutical patents granted in United States of America (USA), which are considered of high relevance, since they deal with medicines and related products commercialized in USA, and also important to the Brazilian market share, i.e., they are able to influence the Brazilian market share by being impeding to Brazilian industries to produce a medicine, for instance.
to pharmaceutical patents, whether in the US or international countries. It also provides data on litigation, tentative approvals, patent expirations, clinical trials, Paragraph IV challenges, top patent holders, and other relevant information. Among the options of search it enables, are included: i) search by pharmacology; ii) search by drug patent expiration, iii) search by application name; iv) by country; v) by trade names; vi) by dosage, vii) by product ingredients; among others. In this work, the crucial search field used was search by patent expiration year, which enabled results restriction to recovery of patents with expiration year from 2018 to 2022, as detailed in methodology section. In order to search for the correspondence of all US patents retrieve in Brazil, Espacenet and INPI databases were used. Espacenet is a free online service developed by the European Patent Office (EPO) for searching patents and patent applications worldwide and provides complete information on patent families including Brazilian patent documents since 1974 (see: https://www.epo.org/searching-for-patents/technical/patent-additions.html). In Espacenet, it was performed in accordance to the indications of Martin et al. [27] in which they advise to follow general search steps: i) analyzing the invention, by analyzing the patent’s claims and constructing a search table for primary results compilation; ii) performing the search using the chosen strategy (keywords, period of interest, classification, Booleans, etc.); and iii) evaluating the documents retrieved. With this regard, Espacenet was used to find the correspondent documents filed in Brazil by searching the US patent numbers already retrieved by Drug Patent Watch.

When a Brazilian document was not localized in the US patent family of Espacenet, double searching was performed at INPI database to retrieve the correspondent document filed in INPI, if any. The search fields employed were i) priority number, ii) priority date, iii) inventor, iv) applicant and v) PCT application number (when the original US patent document was related to a PCT application). Using this combined strategy, it was possible to retrieve the Brazilian correspondence, one by one, of the first retrieved US-patents. INPI database was also used to access information regarding: i) patent status in Brazil; ii) patent effective date in Brazil; iii) subject-matter claimed, considering the claims set as granted or the latest claims set valid during prosecution history; and iv) filing date in Brazil, to determine the patent term by applying the Art. 40, when it was the case.

The recovered data were organized in an intricated spreadsheet using mainly free softwares such as LibreOffice and RStudio.

LibreOffice is a free, open-source office suite, forked (i.e. developed from a copy of source code from another software package, giving rise to a distinct software) from OpenOffice.org (an open-sourced version of StarOffice). It comprises programs for word processing, but also for creating spreadsheets, composing mathematical formulae, diagrams, drawings, among others and it is available in 115 languages [28]. RStudio is a free, integrated development environment (IDE) for R programming language that is used by professionals of several fields for statistical computing and graphics, allowing the analysis of large amount of information, and allowing a variety of data presentation options, as didactic as possible. It is available in two formats: RStudio Desktop, which is a regular desktop application and RStudio Server, which runs on a remote server, allowing access by a web browse. Data analysis, in this work, gave rise to alluvial plots through free and specific RStudio packages obtained from the install package (“package name”) function on the console, available in Comprehensive R Archive Network (CRAN) open access repository [29], which contains all files and documentation to create individual charts and chart combinations.

### 3. Methodology

Data collection and determination of the universe of analysis were defined in accordance with the following methodology. To enhance precision and relevance of patents obtained from the search, refinement was achieved by a loop of feedback results, as stated by Moehrle [30] considering the prior state of art and choosing the relevant set of keywords (or parameters) in English, Portuguese and Spanish languages. The dataset was organized in a spreadsheet that shows the number of patents, title, owners, deposit and expiration dates, claims, country of origin, among others. The recall resulted in 613 patents, which were manually retrieved and evaluated.

#### 3.1. Data selection

The documents qualified for inclusion in selection were defined as US-pharmaceutical granted patents (i.e. valid in US territory) with expiration date from 2018 to 2022. Data were recovered by Drug Patent Watch database (trial access on April 2017). A search was carried out through search field of restriction by patent expiration year, selecting as a criterion patents to be expired between 2018 and 2022.

From this search criteria, 613 (duplicated patent numbers were removed one by one) granted patents in the US related to 546 medications registered in FDA were retrieved.

#### 3.1.1. Correspondence in Brazil

The 613 retrieved patents were organized in a spreadsheet (available at Mendeley Data Repository) to indicate the drug to each respective patent. The one by one analysis in Espacenet and INPI databases, resulted in a list including the US patents with correspondent filing in Brazil, and non-correspondent patents. Upon patent identification, its status, expiration date, and the main subject-matter claimed/protected in Brazil was verified in INPI database and the information was indexed in the spreadsheet.

It is noteworthy that the subject-matter of the patent and the subject-matter of the patent application in Brazil were evaluated, considering the claims set as granted (if it is a patent granted) or the latest claims set in the prosecution history (for rejected applications or under examination).

The correspondence of the drug registered in ANVISA was also checked, one by one, correlating each Brazilian patent document with its respective drug registered in Brazil.

All information presented in this work was updated to July 2020, with information obtained in INPI and ANVISA databases [31,32].

The status of the patent documents in Brazil were indexed in the spreadsheet, considering the definitions in Table 1.

It was also established an indexation related to the main subject-matter claimed/protected by documents filed in Brazil, considering the latest claims set in the prosecution history or in the granted patent (Table 2).

Chart 1 presents the strategy of data selection used in this work.

The effective or estimated expiration date of each patent document filed in Brazil was organized in the spreadsheet and those with expiration date, which can be affected by article 40 of LPI 9279/96, were retrieved. With that, it is possible to evaluate if granted patents had an extended validity or if rejected applications benefited from examination delays.

Data were selected from the spreadsheet, considering: 1) number of US patents that does not have corresponding patents in Brazil; 2) number of US patents with correspondents in Brazil; 3) number of

### Table 1

| Status Indexed          | Meaning                                                                 |
|------------------------|-------------------------------------------------------------------------|
| pending application    | Patent applications with decision on examination still pending           |
| rejected – not concluded| Rejected applications with possibility of appeal, or with appeal decision still pending |
| denied                 | Patents applications definitively rejected                               |
| granted patent         | Patents granted by INPI being valid, extinguished, or in the event of nullity |
| lapsed                 | Abandoned, lapsed or withdraw patent applications                         |

Status of patent documents filed in Brazil. (source: own elaboration).
corresponding Brazilian patents that had been granted; 4) number of Brazilian granted patents with extended validity term considering the art. 40 (LPI); 5) number of corresponding Brazilian applications that has been rejected; 6) number of Brazilian rejected application with late decision and incidence of art. 40 (LPI); 7) number of corresponding Brazilian application that has been abandoned in Brazil and 8) indexation of the patent documents filed in Brazil by the subject-matter claimed/protected.

Data obtained are discussed in the “results and discussion” section.

### 3.2. Statistical analysis of data

The statistical analysis of the collected data was performed using free softwares, LibreOffice and RStudio. LibreOffice Calc and Microsoft Excel were used to store data in a spreadsheet, which were then plotted. The data were processed using the R statistical language integrated with the RStudio software. It was used to plot the graph in Fig. 1 and Microsoft Excel, to plot graphs in Figs. 2 and 3.

#### 3.2.1. Required packages for RStudio

In this work, the RStudio packages “ggplot2”, “ggsci”, “ggalluvial”, “scales” were used to plot data in alluvial graphs; data processing was performed from an external extension table (.csv), used to create a new table, “data.frame”, which listed the values accessed by the data processing functions chosen. The syntax used in data processing is available in Appendix.

### 4. Results and discussion

The universe of analysis comprises the 613 (100%) granted pharmaceutical patents that are valid in US territory (named retrieved US-granted patents) with expiration date between 2018 and 2022. As shown in Figs. 1 and 59% of them have correspondents filed in Brazil. It demonstrates that 41% of US patents have no exclusivity requirement in Brazil, which already raises interesting information about possible market opportunities in Brazil for drugs with exclusivity in the US.

When analyzing the status of patent documents that required protection in Brazil, it is observed that 24% of the universe considered (green flow) were rejected in Brazil, representing 42% of the applications that entered the country, and only 27% (red flow) of these patents, which already have US rights, were granted in Brazil (corresponding to 46% of total patents with protection required in Brazil). It evidences that from the 613 patents granted in the United States, only 27% are also protected in Brazil. On the other hand, this shows that approximately 65% of US valid patents correspond to non-valid patents in Brazil, because they were rejected or they were not filed in Brazil, and therefore are free for exploitation in Brazil, characterizing a pharmaceutical market for these patents subjects more open to competitors in Brazil. Examples of such patents, which are relevant to the pharmaceutical market of both countries, but that were not filed in Brazil are patent US 5,856,336 related to the molecule pitavastatin, the active ingredient of the important antilipidemic medicament commercialized both in US and in Brazil, under the tradename Livalo® and patent US 6,017,927 related...

### Table 2

| Indexation | Meaning |
|------------|---------|
| molecule   | patent documents whose main scope involves the active ingredient molecule or its salts |
| treatment  | patent documents whose main scope involves methods of treatments and therapeutic uses |
| combination| patent documents whose main scope involves the combination of active ingredients relevant to the identified drug |
| pharmaceutical composition | patent documents whose primary scope involves formulations, compositions, dosage forms related to the identified drug |
| devices    | patent documents whose primary scope involves injectors, inhalers, or other devices for administration of the identified drug |
| polymorphs | patent documents whose primary scope involves crystalline forms of the solid active ingredient related to the identified drug |
| processes  | patent documents whose primary scope involves the process of synthesis of the active ingredient of the identified drug or process for preparing the formulation or dosage form related to the identified drug |

Data obtained are discussed in the “results and discussion” section.
to the compound solifenacin, the active substance of the medicament Vesicare® commercialized in both countries for treating urinary conditions.

Data presented in Fig. 1 also shows what was already expected - INPI examination criteria independence. Even having the information that these applications refer to patents already granted in the US, INPI performs its technical examination, based on the parameters of LPI 9.279/96 and grants or rejects the application based on its own analysis, not considering previous results issued by the US office.

Fig. 1 further shows documents that were filed in Brazil, but were abandoned by the applicant (6.5%, blue flow). Such cases reflect only the lack of interest of the patent holder to require protection for his product in Brazil, which also relates to patents free for exploitation in Brazil.

Fig. 2 shows the correlation between the nature of the subject-matter protected by the US patents with correspondents filed in Brazil and the decision on the application issued by INPI. Blue bars show the subject-matter of patents granted by INPI and gray bars show the subject-matter of rejected patents.

From Fig. 2, patents regarding molecules per se are the most easily granted in Brazil, representing 45% of the total of granted patents, followed by patents disclosing compositions, which correspond to 36% of the total of granted patents. 11% of granted patents are related to devices and 3% to processes. Although the number of granted patents regarding molecules (45%) significantly exceeds the number of rejections (12%), this amount of rejections is relatively high, considering patentability of molecules (new chemical compounds) are often less questionable, unless the compound is not new. It is expected that patentability opinion of USPTO and INPI should be the same, as predicted in Brazilian and American legislations, however, it is surprising that, in these cases, INPI had a distinct position from that of USPTO. The reason for that is the distinct criteria to evaluate inventive step of these
inventions, resulting in rejections.

Corroborating this finding, rejection of applications related to composition accounts for 43%, which is even higher than the number of granted patents regarding compositions (36%). Furthermore, patents applications regarding combinations and polymorphs, together, account for 2% of the number of granted patents, and 16% of rejected patents.

It is noteworthy that the number of rejected patents regarding methods of treatment significantly exceeds the number of granted patents, for the logical reasons of LPI 9279/96 application, which provides that methods of treatment are not considered invention, (art. 10, item VIII). The reason for the 3% of patents related to “methods of treatments” being granted in Brazil are due to the possibility of amendment of “method of treatment” claims to “use” claims, by applying the “Swiss-type” formula which is allowed in Brazil, since it refers to a new method for preparing a medicine, as interpreted in INPI’s Resolution 993/2013, not a therapeutic method. In other words, the scope of a claim written such as “using compound X to prepare a drug to treat an illness Y” (Swiss-Type formula) refers to the application of an active substance in the preparation of a medicine to treat a specific disease, not to a therapeutic method.

Also, backlog of patent examination has an important impact on such competitive market where scientific and technological development is daily updated worldwide, since it results in a great number of patents application with pending decision for many years. To demonstrate this high impact caused by the delay in patent examination, Fig. 1 shows the number of granted patents (column 4- red flow) and rejected applications (column 4- green flow) that benefited from art. 40 [3]. Information on granted patents (red flow) in Fig. 1 shows that 76.5% of the granted patent were benefited with term extension (20.7% of the universe of analysis), being, very often, more than 20 years from the filing date. This shows that the majority of granted pharmaceutical patents in Brazil benefit from terms longer than the regular, causing an imbalance in competition of medicaments in Brazil when compared to US.

This study has raised a large number of pharmaceutical relevant patents to the Brazilian market and several examples of such term extension can be exploited. Among them, some medicines of great interest for public health, affected by this long backlog on patent examination, were benefited with patent terms that often reached almost 30 years. An example is patent PI9711437-5, regarding the molecule liraglutide, an antidiabetic agent of the medicament available in Brazil as Victoza® (commercialized by Novo Nordisk). It was filed in Brazil in 1997 and it was granted in 2017 (the year in which it should be expiring by its regular term), but its term, considering the single paragraph of art 40, was fixed up to 2027, leading to it being in force for 30 years. This effect was already expected by the pharmaceutical industry [33], since Brazilian companies must follow up patent status.

Another example is the patent PI0011867-2, which provides protection for the combination of levodopa, carbidopa and entacapone, active ingredients of the drug available on Brazil as Stalevo® (Novartis), for Parkinson’s disease treatment. It was filed in 2000, therefore, it should expire in 2020. However, it was granted only in 2019 and it is valid until 2029.

The patent PI0206509-6, filed on January 22nd, 2002 in Brazil by the US company R-Pharma US Operating LCC, claims protection for the drug known in Brazil as Ixempra®, which is based on the active ingredient ixabepilone, for metastatic cancer treatment. It was granted on October 2nd, 2018, over 16 years after filed, being valid until 2028. This patent document relates to the process to obtain a pharmaceutical composition, but the patent for the molecules per se, derived from epothilone (including ixabepilone), PI9810555-8, was filed in Brazil on June 16th, 1999. Despite having received an office action from INPI on November 17th, 2009 and the company has answered it within the legal deadline, it was sent to prior consent of ANVISA (due to art. 229-C of Law 9279/96) only on February 22nd, 2012 which had been denied on October 2nd, 2012, and until now, this application was not closed by INPI.

Currently, ANVISA’s non-consent must be reported to INPI via a subsidy to the examination and INPI may or may not agree with ANVISA, when defining a patent status [34]. Thereby, if this patent were granted in 2019, it would be in force up to 2029, granting an inappropriate monopoly of additional 11 years beyond its regular term, which would end on June 15th, 2018. Situations such this contribute to create an environment of market uncertainty and insecurity, since whether a patent would be granted or not remain unclear. Even if rejected, up to this date, the application has already enjoyed a market reserve period longer than the regular 20 years.

Also, patent PI0009721-7 (Bristol-Myers) which protects dasatinib, an anticancer molecule was benefited from a term extension of 8 years, since it was filed in Brazil on April 12th, 2000 and granted in 2018. Patent PI0213522-1 claiming the raltegravir molecule, Isentress® (Merck Sharp) active ingredient, for HIV infections treatment, was filed in 2002 and granted in 2017, with a term ending in 2027, an extension of 5 years beyond the normal term.

And patent PI0111596-0 claiming the perampanel molecule, active ingredient of the Fycompa® (Eisai), an anticonvulsant medicine, also benefited from a 7 year-term extension, being filed in 2001 and granted...
in 2016.

These are uttermost examples that illustrate the effect of backlog over the Brazilian pharmaceutical market, being an element that contributes to uncertainties and market imbalances that restrict research and development investments, also exerting great social-economic effect.

These examples demonstrate the harmful effects of late-granted patents with long term extensions, but late rejection decisions cause even more negative effects.

In Fig. 1, green flow indicates that 62.7% of the rejected applications (representing 15.7% of the universe analyzed) had a first instance decision of INPI after 10 years from the filing date in Brazil. This means that patent applications that did not meet the patentability requirements had a long period of expectation of owners right in Brazil, resulting in a market exclusivity reserve of at least 10 years for a patent without merit to be granted. This long period of legal uncertainty discourages competitors to enter this market, which implies that most Brazilian generic and similar medicines companies are uncertain to invest into this market, since companies holding patent applications with controversial patentability, and there is great evidence that INPI scrutinizes patent documents to avoid undeserved granting. However, a delay of this magnitude benefit those who use this strategy.

There is also an impact of patent applications related to drugs of relevance to public health that enjoyed indirect protection periods. This means that term extension creates an expectation of owners’ rights that can be unfulfilled during examination: due to failure of accomplishing deadlines or due to flaws on the patent documents or non-accepted arguments to questioning of INPI, resulting in the patent rejection.

For instance, application PI9814736-6, which claimed the atazanavir bisulfate salt as an incremental innovation to the previously known atazanavir molecule (protected by patent PI9701877-5, which was in force until 2017). It is used to treat HIV infections, it was filed in 1999 and its rejection occurred in 2009. In this case, INPI found lack of patentability requirements, but with a 11-year delay, allowing the drug to enjoy undue indirect protection for all those years.

These delays cause commercial and legal insecurities that prevent a generic drugs from entering the market, as competitors await for patent decisions before eventual release of concurrent medicines. In a fast-developing industry, to prevent concurrent medicines to enter the market is a powerful mechanism to eliminate it. It took place in a patent dispute evoking Kaletra® (AbbVie) and the Brazilian Company, Cristália [35]. Since 2009, there is an action to contest the validity of the patent regarding Kaletra® filed by Cristália. Patent was granted by INPI to AbbVie in 2000 and, after first decisions of invalidity of the patent document, which could encourage companies to focus on a generic for this medicine, finally in 2019, it was considered a valid patent. This strife caused a legal uncertainty that prevented Brazilian generic drugs to be developed and enter this market. Moreover, if the contest had succeed, with the accelerated research on anti-AIDS and the new medicaments that already are in the market, generics for Kaletra® would face a different market dynamics, where Kaletra® would not own the market anymore and the impact of the first generic to be released would be less significant.

There are several other cases of decision pending that influence the Brazilian market. For instance, patent application PI9915986-4, referring to a polymorph of everolimus, the active ingredient of Afinitor® (Novartis), to treat breast cancer, among others, was filed in 1999 and had its first-instance rejection in 2010, enjoying 11 years of uncertainty. Note that, even after the first-instance rejection, the subject-matter is still not in public domain in Brazil, since the applicant continued appealing against the INPI decision in administrative second-instance and by the judicial court. This dispute still did not reach a closure.

Patent application PI9814480-4, which claimed protection for fosamprenavir, active ingredient of Telzir® (GlaxoSmithKline), for AIDS treatment. This application was filed in 1998 and was rejected in first-instance in 2009, enjoying indirect protection through uncertainty about its patentability for 11 years. Not to mention the undue indirect protection for 11 years, while it did not have the first decision in the examination prosecution, the applicant also appeal for second administrative instance before INPI and judicial court and the process was finished in 2017, with the holder resignation. This application enjoyed 19 years of legal uncertainty, almost the term of a patent with merit to be granted.

In this context, Fig. 3 shows the subject-matter claimed/protected by the patent documents with delayed decisions, thus, enjoying indirect protection. It is observed that rejections of applications regarding to pharmaceutical compositions are highest (32%), followed by method of treatment (22%) and polymorphs (13%). Such subjects are commonly within the concept of evergreening, since they exemplify trivial incremental innovations.

It is inferred from Fig. 3 that, while most primary patents (referring to molecules) were granted with a longer term in Brazil, secondary patents (i.e. patents referring to use, polymorphs, compositions, processes, etc.) also benefited from longer protections, either by extended terms of granted patent or by excessive delay on examination of applications those should be rejected.

It was demonstrated that innovative industry can benefit from delays in patent examination decisions, on the other hand, companies may not fully enjoy the right conferred by their patent portfolio, as it is not properly assessed and used to influence the market.

In an industry strongly related to scientific development, especially in the fields of chemistry, pharmaceuticals, packaging and materials, among many other fields of science and technology, the lack of market growth due to lack of security also leads to little investment in research and development due to uncertain financial return. This is harmful to the innovation cycle in Brazil in several other areas, as well. Therefore, this discussion should be taken into consideration for the development of public policies.

Actions to fight backlog are urgent in Brazil, and it is noteworthy that INPI has recently launched action plans that enable the use of examination reports already performed by foreign patent offices for a corresponding patent outside Brazil.

In the report entitled “pre-examination in patent applications”, INPI presents a formal requirement that enables the applicants themselves to make amendments to their patent applications, considering patentability reports already issued for the referred document abroad. This action has already demonstrated a productivity gain of 17.2% in 2018 [36].

This pilot project was proposed to attend the INPI’s resolutions 240 and 241 of July 2019 [25], which formalized an accelerated examination procedures for patent applications filed until December 31st, 2016 and it will also consider searches conducted by foreign offices. This procedure is recent and there is still no data on its effects to combat backlog, however, INPI intends to reduce 80% of the backlog in 2 years, as they have been announced.

It is clear that INPI is aware of its role on the effects presented here. Although such cases had already influenced the market and they can still influence it for a while, as there are pending application still accumulating with more than 10 years without exam, it is hoped that in the near future, such examples will be exceptions to the INPI examination procedures.

5. Conclusion

Data presented in this work evidenced that the Brazilian pharmaceutical market share is highly driven by the eccentric treatment patent applications go through in Brazil, due to historical factors of hushed legislation harmonization that had effects on the Brazilian pharmaceutical industry development, focused on generic drugs production.
Considering that innovation and technological developments in this market share is not headed by Brazilian industries, but by foreign, specially American industries, a thorough analysis of the status of patents applications filed in Brazil, corresponding to valid patents in USA and the way legislation is applied to them evidence their impact in the Brazilian pharmaceutical market share was carried out. It is noteworthy that in a universe of analysis of 613 US pharmaceutical-granted patents, with expiration date being from 2018 to 2022, nearly half did not requested filing in Brazil, which is attributed only to industrial strategies.

Among the patent applications that were filed in Brazil, there is a great percentile (41%) of patent rejections in Brazil from those that have already been considered granted in the USA, which is attributed to the independence of examination procedures of INPI and lead to a great variety of patented procedures and products that are free to be operated by generic drugs companies in Brazil. It is noteworthy that rejections in Brazil of granted patents in US are due to national regulation differences, especially regarding to patentability requirements, which considers, for instance, methods of treatment as patentable in US and not patentable in Brazil. Surprisingly, there is a significant proportion of patents regarding to molecules (new chemical compounds), which are patentable in both countries, that were rejected in Brazil, once again demonstrating the independence of examination carried out by INPI and an important effect on the market share, since products of high aggregated value in USA are free to be exploited by generic drugs companies. These findings suggest the openness of the Brazilian pharmaceutical market to competitors that are able to take advantage of the large number of drugs with patent protection in the United States.

Although these aspects point to opportunities of development pharmaceutical industry in Brazil, the analysis performed in this work also highlighted the effects of the delays on patent examination due to the enormous backlog of patent examination in Brazil, which enable such an expectation of owner’s right that distort the direction of the market, in part due to the provision of article 40 of law 9279/96.

The significant influence of decision delays by INPI causes a legal uncertainty on the market that inhibits investments of domestic companies, inhibiting its growth and preventing it to move from an essentially generic and similar industry to an innovative industry that invests in research and development. Delayed decisions also instigate ever-greening strategies by patent-holding industries, which generally are multinational and cause an improper market reserve for a long period, even for relevant drugs to public health. It also indicates that the measures to combat the backlog of patent examination recently presented by INPI are urgently needed to turn the Brazilian pharmaceutical market share attractive and the national industry, competitive. It is also needed to enable the proposal of efficient public policies aimed at encouraging innovation, scientific research and technological development in Brazil, especially in the emergency situation of COVID-19 pandemic.

CRediT authorship contribution statement

T. D. M. Paes: Conceptualization, Methodology, Investigation, Validation, Formal analysis, Writing - original draft, Writing - review & editing, Resources. Lucas F. Aguiar: Data curation, Formal analysis, Resources, Validation. Tatiana D. Martins: Methodology, Validation, Data curation, Formal analysis, Writing - original draft, Supervision, Visualization, Funding acquisition, Writing - review & editing, Project administration.

Acknowledgment

Authors thank Capes for scholarships.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.wpi.2020.101999.

Appendix

For the data processing and the alluvial plot, it was necessary to use the R language in a development environment such as RStudio, freely available. RStudio packages employed to obtain the alluvial plot were ggplot2, which is the main framework; “Ggsci”, which is the color definition package; “Ggalluvial”, the specific package for building alluvial graphics and “scales” for determining the position of characters in the figure. Language used was Portuguese. Codes used to access the elected treatments are listed below:
= verbete

```r
library(ggplot2)
library(ggsci)
library(ggalluvial)
library(scales)
```

= verbete

The database to plot the chart was organized into a .csv file extension and is presented in Table 1A. In RStudio, the file was interpreted using the “read.csv” function. From these data a new table was created using the “data.frame” function that was used for the effective construction of the alluvial graph.

### Table 1A
Number of patent documents filed used to plot US patent flow in Brazil, correspondence in Brazil, status of the applications filed in Brazil, Brazilian application procedure flows and Brazilian applications decisions

| Document | FilingBR | Destiny | Journey | Quantity |
|----------|----------|---------|---------|----------|
| U.S. Patent | Yes | Granted | Granted w/extension | 125 |
| U.S. Patent | Yes | Granted | Other granted | 38 |
| U.S. Patent | Yes | Rejected | Rejected after 10 years | 92 |
| U.S. Patent | Yes | Rejected | Other rejection | 57 |
| U.S. Patent | Yes | Abandoned | Abandoned | 39 |
| U.S. Patent | Yes | Without decision | 10 years without decision | 15 |
| U.S. Patent | No | No BR filing | No BR filing | 253 |
The codes used to plot data from this information in table IA are as follows:

```r
verbete
```

```
```

```r
uspat.df <- read.csv("US-patents.csv")
Quantidade <- uspat.df$Quantidade/sum(uspat.df$Quantidade)

quantidade

```

```r
uspat.data <- data.frame(
    uspat.df$Documento, uspat.df$DepositoBR, uspat.df$DataCitação, uspat.df$DataJornada,
    Quantidade = Quantidade)
```

```r
verbete
```

The graph is plotted from the conjunction of some functions, the main one being “ggplot” which defines alluvial graph columns from the “uspat.data” table. The other functions result in the best visualization of the information.
References

[1] Denis Borges Barbosa, Normas históricas da propriedade industrial. http://www.denisbarbosa.addr.com/paginas/leis/leis_historicas.html.

[2] http://www.planalto.gov.br/ccivil_03/Leis/L5772.htm.

[3] Brazilian Industrial Property Law (Lpi) 9,279, of May 14, available at: https://www.wipo.int/edocs/lexdocs/laws/en/br/br003en.pdf, 1996. accessed on November 2019.

[4] Trips Agreement, available at: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf. accessed on May 2019.

[5] D.B. Barbosa, Uma introdução à propriedade intelectual. 2a edição. Rio de Janeiro: Lumen Juris, Hermes advogados. Acordo TRIPS – Aplicação e Vigência no Brasil, 2003. July 17th, 2014. available at:http://hermesadvogados.com.br/2014/07/17/acordo-trips/.

[6] R.R. Dubex, Um balanço da evolução recente das leis de patentes no Brasil: os efeitos do Acordo TRIPS, Revista Jus Navigandi, ISSN 1518-4862, 15, May 2019, https://jus.com.br/artigos/17269/um-balanco-da-evolucao-recente-das-leis-de-patentes-no-brasil-os-efeitos-do-acordo-trips, 2010.

[7] E. Mercadante, L. Hasenclever, J. Paranhos, Um estudo da tramitação de patentes farmacêuticas concedidas pelo INPI pós-TRIPS, in: II Encontro Nacional de Economia Industrial e Inovação, Blucher, São Paulo, 2017, pp. 776-791, https://doi.org/10.5151/enei2017-43, 4(2).

[8] R.R. Almeida, O exame de mérito das patentes. Revista Facto. ABIFINA, sixth ed., 2007, 03, http://www.abifina.org.br/revista_fatto_materia.php?id=185, on May 2019.

[9] S.S. Garcz Júnior, A evolução de pedidos de patente com análise pendente noINPI: construindo alternativas para proteção do depositante e diminuição do backlog. Dissertation, São Cristóvão – SE, Brasil, 2015.
[10] R.B. Andrade, ‘Backlog’ condensa paiz ao atraso. O Estado de S.Paulo, available at: https://economia.estadao.com.br/noticias/geral, backlog-condensa-paiz-ao-ataraso,70002049626, October 3rd, 2017. accessed on May 2019.

[11] Inpi. Relatório de atividades, Available at: http://www.inpi.gov.br/sobre/estatisticas, 2018. Accessed on August 2019.

[12] http://www.planalto.gov.br/ccivil_03/leis/l9782.htm.

[13] P.N. Figueiredo, Acumulação tecnológica e inovação industrial, São Paulo em Perspect. 19 (1) (2005) 54-69, 2005.

[14] M. Bell, K. Pavitt, Ind. Corp. Change 2 (2) (1993) 157-210, https://doi.org/10.1093/icc/2.2.157.

[15] D.B. Barbosa, A inexplicável política pública por trás do parágrafo único do art. 40 da Lei de Propriedade Industrial, available at: http://www.denishbarbosa.addr.com/arquivos/propriedade/inexplicavelPoliticaPublica.pdf, 2013. Accessed on May, 2019.

[16] G.F. Leonaros, R.S.S.R. Aguilal, Nota sobre os efeitos da publicação da anotação de cessão de registro de marca em face das inconveniências do backlog do INPI, Rev. ABPI 143 (2016) 43-56.

[17] S.S. Garecz Júnior, J.J.S. Moreira, The backlog of patent in Brazil: the right to reasonable duration of the administrative procedure, Rev. Direito GV 13 (1) (2017) 171-203, https://doi.org/10.1598/2317-61722017008.

[18] V. Rodríguez, The backlog issue in patents: a look at the European case, World Patent Inf. 32 (4) (2010) 287-290, https://doi.org/10.1016/j.wpi.2009.11.002.

[19] M. Mejer, B.P. Poterie, Patent backlogs at USPTO and EPO: systemic failure vs deliberate delays, World Patent Inf. 33 (2) (2010) 122-127, https://doi.org/10.1016/j.wpi.2010.12.004.

[20] M. El-Said, The road from trips-minus, to trips, to trips-plus, J. World Intellect. 17 (1) (2014) 105-171.

[21] S.S. Garecz Júnior, J.J.S. Moreira, The backlog of patent in Brazil: the right to reasonable duration of the administrative procedure, Rev. Direito GV 13 (1) (2017) 171-203, https://doi.org/10.1598/2317-61722017008.

[22] M.L.A. Silva, A.C.M. Brito, A.M.S. Antunes, Controversies on the patent protection–credits and the applicability of tributary law: uncertain and undefined, in: Anais do XVII Congresso Nacional do CONPEDI, 2008, pp. 2265-2283.

[23] A) Inpi Resolution PR no 217, May 3rd, http://www.inpi.gov.br/sobre/legislacao-1, 2018. August 2019; B) Inpi resolution PR no 239, of July, 4th, http://www.inpi.gov.br/sobre/legislacao-1, 2019. accessed on February, 4th, 2020.

[24] B) Inpi Resolution PR no 240, July 3rd, http://www.inpi.gov.br/sobre/legislacao-1, 2019. accessed on February, 4th, 2020.

[25] A) Inpi Resolution PR no 241, July 3rd, http://www.inpi.gov.br/sobre/legislacao-1, 2019. August 2019; B) Inpi Resolution PR no 240, July 3rd, http://www.inpi.gov.br/sobre/legislacao-1, 2019. August 2019.

[26] Inpi, Plano de combate ao Backlog. http://www.inpi.gov.br/menu-servicos/patentes/plano-de-combate-ao-backlog.

[27] E. Martin, A.C. Derrien, How to apply examiner search strategies in Espacenet. A case study, World Patent Inf. 54 (2018) S33-S43, https://doi.org/10.1016/j.wpi.2017.06.001.

[28] The Document Foundation, LibreOffice, available at: https://www.libreoffice.org/download/download/.

[29] Cran, The Comprehensive R Archive Network. [S.l.: s.n.], Available at: https://cran.r-project.org/. Accessed on June, 2019.

[30] M.G. Möelbre, Relax and sample: thoughts about the recall of a patent search, World Patent Inf. 54 (2018) A1-A3.

[31] Inpi database. https://gra.inpi.gov.br/petF/jsp/patentes/PatenteSearchBjsp. Available on May, 2019.

[32] Anvisa database. http://portal.anvisa.gov.br/biblioteca/bases-de-dados.

[33] G. Salerno, The consequences of 'double examination' for pharmaceutical patent applications in Brazil, Pharmaceut. Patent Analyst 6 (2) (2017) 49-51, https://doi.org/10.4155/ppa-2017-0005.

[34] Portaria Conjunta n° 1 April 12nd, Available at: http://www.in.gov.br/materia/asset_publisher/KujrwO7rZC2Mb/content/id/20163436, 2017. Accessed on May, 2019.

[35] C. Baima, Patente de droga para tratar de Aids no Brasil gera briga judicial entre laboratórios. O Globo, available at: https://oglobo.globo.com/sociedade/saude/patente-de-droga-para-tratar-de-aids-no-brasil-gera-briga-judicial-entre-laboratorios-12712206, 2014. Accessed on May 2019.

[36] C. Vaidman, M.P. Santos Júnior, V.L. Latsch, D. Barros Júnior, Pré-exame nos pedidos de patentes – avaliação dos resultados – INPI - DIRPA, available at: www.inpi.gov.br/menu-servicos/arquivos-dirpa/PreExameRelatorioExecutivo.pdf, 2018. Accessed on May, 2019.

Prof. Tatiana Martins is associate professor in the Chemistry Institute of the Federal University of Goias - Brazil. Member of the Global Young Academy (GYA) and of the Unesco chair for Materials and technologies for energy conversion, saving and storage (MATECSS), her research interests are on materials development for energy conversion, sensors as well as drug delivery and photodynamic therapy. As an intellectual property specialist, she also develops research on intellectual property in the pharmaceutical, chemistry and materials fields.

MSc. Thalita Paes is CEO of Patent Abilit Industrial Property company. Intellectual property specialist, she worked in several pharmaceutical industries creating and developing their intellectual property departments. She is invited professor in graduate courses and is intellectual property specialist and researcher in Federal University of Goias.
Update

World Patent Information
Volume 71, Issue , December 2022, Page

DOI: https://doi.org/10.1016/j.wpi.2022.102136
Erratum regarding missing Declaration of competing interest statements in previously published articles – Part 2

Declaration of Competing Interest statements were not included in the published version of the following articles that appeared in previous issues of World Patent Information:

1. “News on patent, trade mark and design databases on the Internet” [World Patent Information, 2020; 61:101962] 10.1016/j.wpi.2020.101962 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

2. “Zip’s law applications in patent landscape analysis” [World Patent Information, 2020; 64:102012] 10.1016/j.wpi.2020.102012 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

3. “News on patent, trade mark and design databases on the internet” [World Patent Information, 2020; 62:101973] 10.1016/j.wpi.2020.101973 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

4. “Literature Listing” [World Patent Information, 2019; 58:101902] 10.1016/j.wpi.2019.101902 The author declares that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

5. “Iron and steel patents: The sinews of the GB Industrial Revolution” [World Patent Information, 2019; 58:101901] 10.1016/j.wpi.2019.101901 The author declares that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

6. “Literature Listing” [World Patent Information, 2019; 56:1881] 10.1016/j.wpi.2019.01.001 The author declares that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

7. “Literature Listing” [World Patent Information, 2019; 57:1897] 10.1016/j.wpi.2019.03.009 The author declares that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

8. “Measuring technological patent scope by semantic analysis of patent claims – An indicator for valuating patents” [World Patent Information, 2019; 58:101906] 10.1016/j.wpi.2019.101906 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

9. “Forty years of World Patent Information: A bibliometric overview” [World Patent Information, 2020; 64:102011] 10.1016/j.wpi.2020.102011 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

10. “Automatic generation of Markush structures from specific compounds” [World Patent Information, 2019; 57:1894] 10.1016/j.wpi.2019.03.006 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

11. “Identification of US-pharmaceutical patents expiring between 2018 and 2022 and their effect on the Brazilian domestic market” [World Patent Information, 2020; 63:101999] 10.1016/j.wpi.2020.101999 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

12. “Patent data analytics for technology benchmarking: R-based implementation” [World Patent Information, 2020; 60:101952] 10.1016/j.wpi.2020.101952 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

13. “Towards the development of scales to measure patent management” [World Patent Information, 2019; 58:101909] 10.1016/j.wpi.2019.101909 The authors declare that they have no known...
competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

14. “Survey of and modular construction possibilities for maturity approaches in the field of patent management” [World Patent Information, 2019; 57:1882] 10.1016/j.wpi.2019.01.002 The authors, have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

15. “Embrace Artificial Intelligence technologies for advanced analytics and management of intellectual properties” [World Patent Information, 2020; 61:101970] 10.1016/j.wpi.2020.101970 The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.