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RESEARCH ARTICLE

The Relevance of Regional Specificities of Intellectual Property Regulations for Pharmaceutical Industries: Brazilian Law Changes That Immediately Affected Crucial US-Pharmaceutical Patents with Correspondents in Brazil

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ABSTRACT
In May, 2021, the single section of title 40 of the Brazilian industrial property act (LPI 9.279/1996), which guaranteed a minimum term of 10 years to a granted patent was found unconstitutional by a decision on the Direct Act of Unconstitutionality #5529/DF (ADI5529/DF). It resulted in crucial and immediate effects, especially in Brazilian pharmaceutical market, affecting the and the international interests of pharmaceutical companies in the Brazilian market. Such law changes, although being a national matter, but having international consequences must be under watch worldwide, since they are not arbitrary, but the result of the power that each country has to exert their legal freedom. Therefore, considering the information available on patent databases, this work evidences such effects, evaluating American pharmaceutical patents with correspondents in Brazil that had been benefiting from a particular provision of the Brazilian intellectual property law, the single section of title 40, which provide a minimum term to granted patents that took too long to be evaluated and should be an exception provision. From those data, we have found that 75% of those patents were affected in expressive ways, for instance, 38% of them immediately expired, and 33% had their terms drastically shortened. This work also shows that only 32% of those patents were not affected by the decision of unconstitutionality of single section of title 40 of the Brazilian law. This evidences a severe impact on the ways the national pharmaceutical companies will work, especially because this change immediately open to them several opportunities to explore drugs that, until the day before the decision, were in force and now are at public domain. However, they are not prepared to innovate and it may not be able to supply the market. On the other hand, multinational companies may withdraw from the market, since that are no longer working under a monopoly. The information disclosed in this work show that it will severely affect the Brazilian pharmaceutical market from now on and draws the attention to the need of companies to be aware of all national laws regarding to the market of interest.

Keywords: pharmaceutical patents, ADI5529/DF, section of title 40, Industrial Property Brazilian Act, Brazilian pharmaceutical industry.

INTRODUCTION

Patent documents are crucial as information source to several research and development strategies, as well as to commercial strategies, in addition to their fundamental social function. They provide a temporary monopoly for the investor to explore its intellectual products, as incentive that further fosters new research and development, thus moving the innovation cycle, although it is not always well accepted because it is an exception to laws of free competition. [1-3]. In Brazil, patents confer property rights guaranteed by the Brazilian Constitution [4], therefore, provides a restricted temporary privilege, respecting social interests.[1] The effectiveness of patents legal effects is guaranteed by the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) [5] and by national intellectual property regulations regarding based on it.

In a previous work [6], we showed that the Brazilian industrial property act, LPI9279/96 [7], in its title 40, presents a single section as a provision to correct distortions in the patent rights due to delays on examinations by the Brazilian Industrial Property Office (INPI).[8,9] In Brazil, before TRIPS adhesion, pharmaceutical products were not patentable. Pressed by foreign interests in the pharmaceutical market, Brazil hushed to adopt TRIPS, which affected INPI operation and a large backlog of patent application under examination was instantly created. [8,10,11]

In order to immediately adapt its national regulation to TRIPS, when became a member of WTO, Brazil had neglected its right to the transitional periods applied to developing countries adhesion stated in TRIPS title 66.1, [12-14] which assured developing countries 10 years from 1995 to fully adhere to TRIPS, plus an additional 10-year transition period (up to 2016) for pharmaceutical product patents, assured in WTO Ministerial Meeting in Doha in 2001 [15]. Moreover, in 2015, a new transition period was established, extending adhesion to TRIPS to July 1st, 2034. [5]

In addition, LPI9279/96 transitional titles instituted new categories of patent applications: *mailbox* and *pipelines*, which were only recently assigned. It also provides that a prior consent of the Brazilian Surveillance Agency (ANVISA) is needed to register drugs in Brazil, being essential to patent examination. All these mechanisms contributed to the long backlog that was previously thought to be compensated by the single section of title 40 of LPI9279/96, which states that, although a patent term is of 20 years (for inventions, and 15 years for utility models) from the filing date, its minimum term is 10 years after granted (or 7 years for utility model) by a TRIPS-plus provision. [5,8]

Since then, the single section of title 40 of LPI9279/96 constitutionality had been questioned, since title 44 guarantees to a patent applicant the right to inhibit an unauthorized third party to explore their protected technology.

The scenario of a reinforced backlog of patent examination by more patent applications constantly issued, provided the development of an industry essentially dedicated to generic drugs production, inhibit investments in new products development.

In addition, pharmaceutical companies, aware of this long backlog, make use of discussible strategies to inhibit concurrence, such as, patents evergreening,[16-18] characterized by multiples and successive patent applications seeking protection for trivial innovations; or patent fencing strategies, in which a company makes use of competitors key technologies and limit their business by patenting technologies around the competitor, restricting its opportunities and result in an uncertain industrial environment. Evergreening provides an even more problematic uncertainty due to the unpredictable term extension conferred by the provision of the single section of title 40 of LPI9279/96. This extension should be a temporary exception to the law but, it is, in fact, a routinely provision to pharmaceutical patents in Brazil.[6]

In this context, an important direct act of unconstitutionality filed in the Brazilian Federal Court of Justice (STF) was decided in mid-May, 2021, effectively considering unconstitutional the single section of title 40 and immediately affecting the national pharmaceutical industry. In this work, the situation of patents that had prior benefited from the single section of title 40 of LPI9279/96 and their actual situation after the decision on the Direct Act of Unconstitutionality number 5529/DF (ADI 5529/DF) and the current scenario of the pharmaceutical Brazilian market are analyzed.[19,20]

METHODS

This is a case study of the influence of intellectual property rights as applied in Brazil, and the legal freedom that are provided by any national regulation exert on a very sensible market such as the pharmaceutical, which is dominated by multinational companies and dependent of patent enforcement. Data selection and determination of the universe of analysis were defined accordingly to the following:

Data selection

From the universe of 613 American (US) pharmaceutical granted patents with expiring date from 2018 to 2022, determined in a previous work [6], US-patent applications which presents correspondents in Brazil are 363 (59%). From those,

257 (76%) patent documents refer to drugs effectively registered by ANVISA, which is required to enable drug commercialization. From these 257 patents, 128 (49%) are patents subjected to the single section of title 40 of LPI9279/96 and susceptible to the effect of the ADI5529/DF decision, either due to (1) the fact that they refer to patents already granted by INPI (even if already expired), or (2) because they refer to patent applications still under examination.

Data used in this work were recovered by a specialized database, *Drug Patent Watch*, which relates pharmaceutical patents to their corresponding FDA-registered drugs.

Validity in Brazil

The 613 retrieved US-patents were correlated to the respective FDA-registered drug and the respective US-granted patent. Patent searches were conducted in Espacenet and INPI databases, then, one-by-one analysis was performed to show the US-patents with a correspondent filing in Brazil. Upon patent identification, patent information such as status, filling date, expiring date (before ADI5529/DF decision), the main subject-matter claimed/protected in Brazil, were retrieved by INPI database and information were indexed (see Data Reference). From there, ANVISA´s registration was verified by correlating each Brazilian patent document to its respective drug as registered in Brazil. Then, crucial patent documents (i.e., Brazilian patents correlated to drugs registered in ANVISA) were selected from the indexed information, revealing the 257 crucial patents to the Brazilian pharmaceutical market. They were evaluated with respect to their status in INPI database, resulting in 128 patent documents that could be influenced by the decision on ADI5529/DF in Brazil. These documents are, therefore, the subject of this work. They current terms were verified to evaluate any changes upon ADI5529/DF decision.

All information on patents documents presented in this work was updated to June 2022, with information obtained in INPI and ANVISA databases. [21,22] This robust information was analyzed and it is shown in Figures 1 to 5, as follows.

In the alluvial plot of Figure 1, it is shown: A) the determined universe of patent documents of interest in this work, which is the 128 patent documents subject to the effects of the single section of title 40 of LPI9279/96 (column 1). B) From this universe, the eventual term extensions these documents were subjected to, were determined by one-by-one analysis (column 2). C) Patents were analyzed, considering any influence of the decision on ADI5529/DF on them (Column 3) and D) the current status of these documents, evaluated one-by-one, are shown in column 4. They are indexed according to table 1.

Table 1. Status index of patent documents of interest in this work.

Indexed Status	**Meaning**
Expired	All expired applications, despite affected or not by the decision on ADI 5529/DF.
Rejected	All rejected applications, even with appeal still pending
In force	Granted patents and applications that remained valid after the *ex tunc* decision on ADI 5529/DF, even with term reduction.
Special cases	Punctual cases in which the effect of the *ex tunc* decision on ADI5529/DF is worth to analyze.

Also, data were analyzed with respect to the *ex tunc* (meaning it is retroactive) decision on ADI5529/DF as 1) *term reduction*, 2) *not affected* and 3) *immediate extinct* and this analysis is presented in Figure 3.

It was also established an indexation related to the main subject-matter claimed by documents of relevance to this work. This indexation is presented in Table 2.

Table 2. Indexation of the subject-matter claimed in patent application of interest in this work.

Indexation	Meaning
Molecule	Patents whose main scope is the active ingredient, molecule or its salts.
Combination	Patent documents related to the combination of active ingredients relevant to the identified drug.
Treatment	Patent documents related to treatment methods.
Pharmaceutical composition	Patents related to formulations, compositions, dosage related to the identified drug.
Others	Comprises devices (patent documents whose main scope are injectors, inhalers, or other administration devices); polymorphs; processes related to the drug production.

The indexation in Tables 1 and 2 were used in all plots presented in Figures 1 to 6, according to the focus to be analyzed. These analyses are discussed in the "results and discussion" section.

Statistical data analysis

The statistical analysis of the collected data was performed by MicrosoftExcel and OriginLab softwares. MicrosoftExcel was used to store data in a spreadsheet, which were then plotted. Alluvial plot presented in Figure 1 allows the simultaneous analysis of large amount of information, and a variety of data presentation options, as didactic as possible. OriginLab was used to plot the alluvial in Figure 1 and Microsoft Excel, to plot graphs in Figures 2-6.

RESULTS

Considering the universe of 613 patent documents analyzed in a previous work [6], which correspond to the total US-granted patents with expiring date between 2018 and 2022, 363 (59%) present a correspondent filing in Brazil. From those, 257 (76%) patent documents are related to drugs registered by ANVISA, therefore, being relevant patents in Brazilian pharmaceutical market. Data evidenced that 128 (49%) of them were influenced somehow by the single section of title 40 of LPI9279/96 and, therefore, they consist of our study subject, since their terms must had changed by the decision on ADI5529/DF.

As the single section of title 40 of LPI9279/96 was a corrective measure, to minimize the effects of delays in patent reviews and guarantee them a minimum term of 10 years, data show that from those 128 documents, 96 patents (75%) presented extended terms due to the provision of the single section of title 40. This large amount of extended-term patents evidences that this TRIPS-plus provision, proposed to be an exception, was, in fact, the actual rule.

However, it is noteworthy that as the Brazilian Supreme Court (*Supremo Tribunal Federal – STF*) determined that the decision on ADI5529/DF is an *ex tunc* decision, meaning it will retrogress, to the technological field of pharmaceutical patents of products and processes, the term extension discrepancy was immediately corrected. Figure 1 informs about patent documents that had their term affected by the provision of the single section of title 40 and/or the decision in the ADI5529/DF.

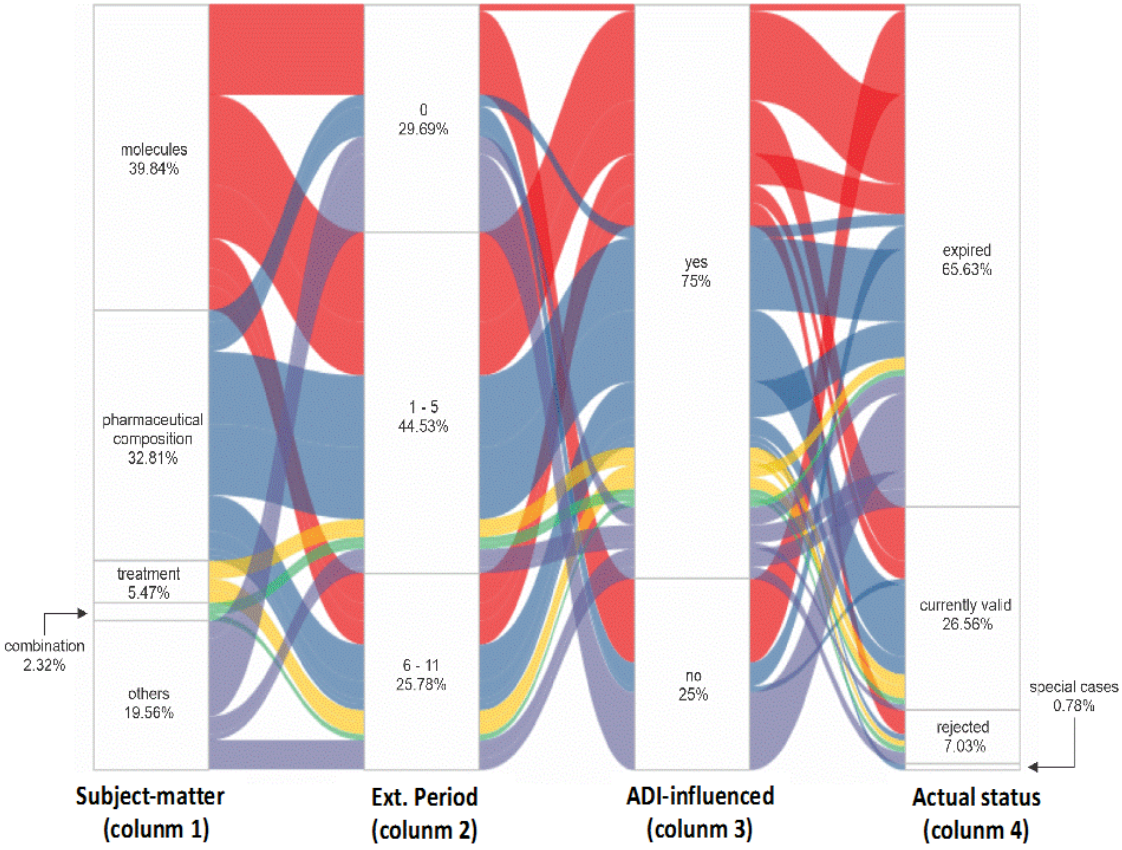

Figure 1: Alluvial plot presenting the subject-matter (column 1), term extension period (Column 2), patents in (Column 3) and the current status of the 128 patent documents that benefited from single section of title. 40 of LPI (Column 4).

Figure 2 presents the term extension expectations on patent applications that were found unmeritorious after examination periods longer than 10 years. It shows that 44% had a term extension expectation of more than 9 years.

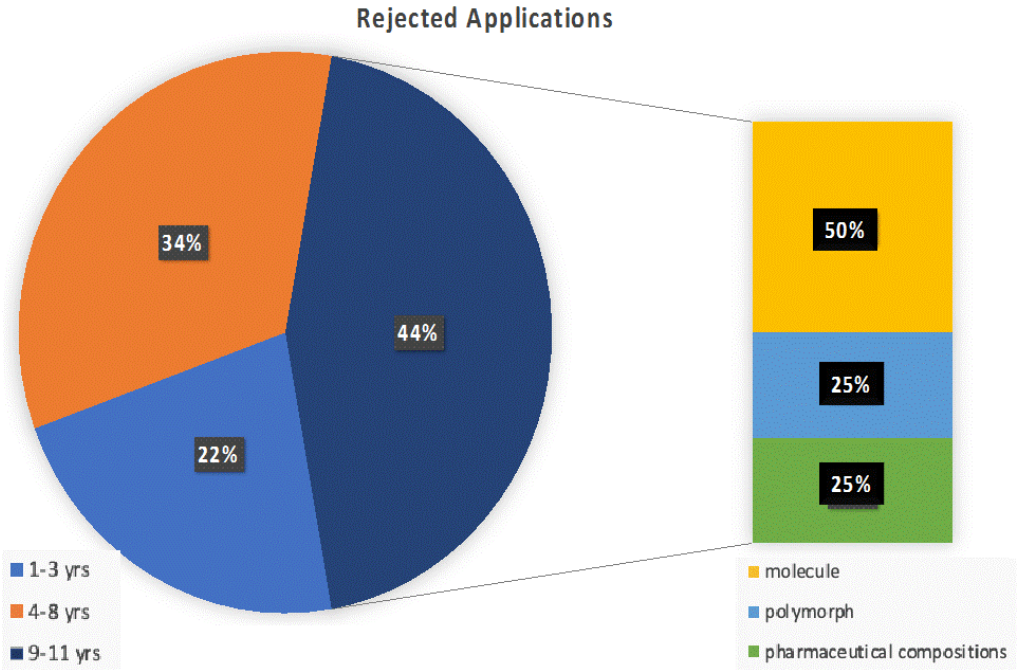

Figure 2. Rejected patent applications after more than 10 years of examination. Main plot: term extension expectation of (royal blue) 1 to 3 years; (orange) 4 to 8 years and (dark blue) 9 to 11 years of term extension. Insert: Subject-matter of patent applications with 9 to 11 years of extension. (yellow) molecules; (light blue) polymorphs and (green) pharmaceutical compositions.

Figure 3 shows that 75% of the patent documents that benefited from term extension suffered an immediate term reduction with the *ex tunc* decision on ADI#5529, and 38% of these documents with reduced terms were extinct from the decision date.

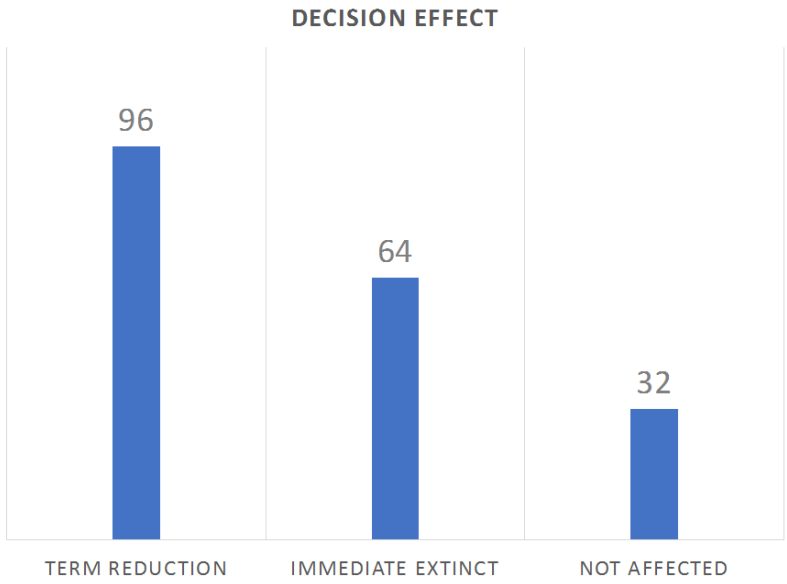

Figure 3: Effects of the decision on ADI5529/DF on patent documents filled in Brazil.

Figures 4A and 4B present the term extensions of patent applications related to molecules and pharmaceutical compositions before the decision on ADI5529/DF. They show that less than 5% of these documents did not benefit from a significant term extension.

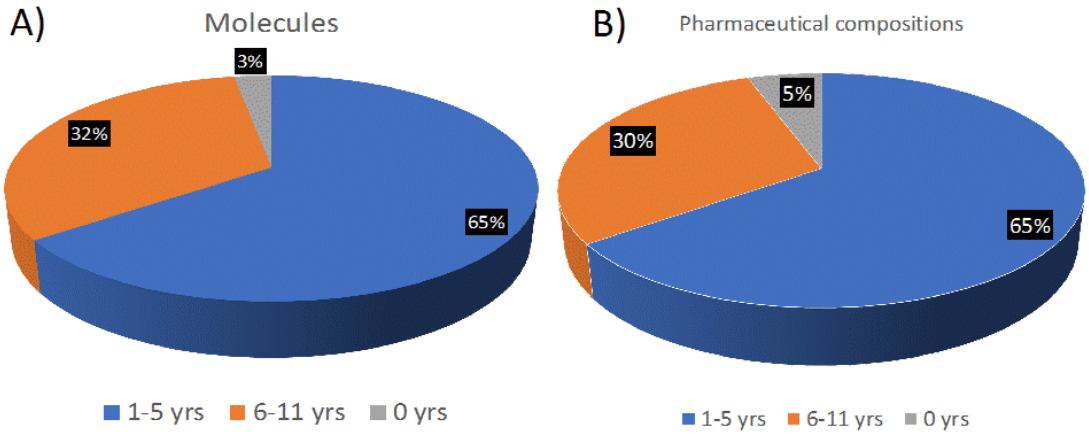

Figure 4: Term extensions of patent applications related to A) molecules and B) pharmaceutical compositions, provided by single section of title 40 of LPI 9279/96.

Also relevant is to determine the subject-matter of patent applications in analysis. Figure 5 shows the subject-matter of patent applications that were granted after 10 years of examination.

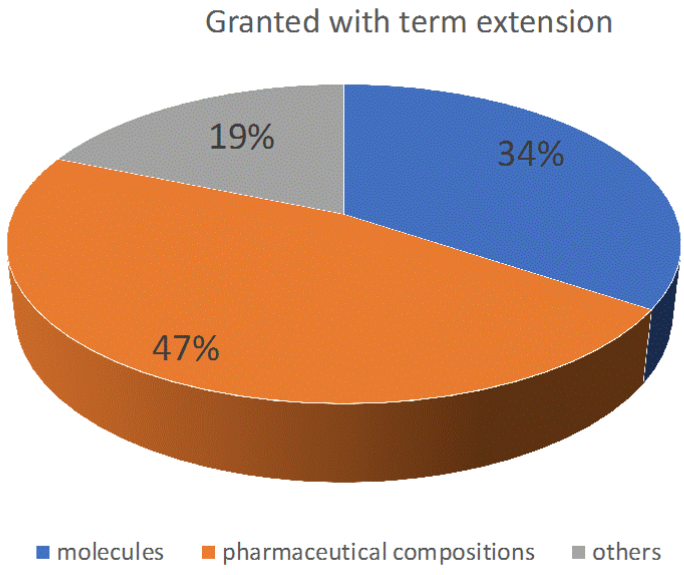

Figure 5. Subject-matter of patent applications granted after 10 years of examination: Pharmaceutical compositions (orange); molecules (royal blue); others (gray).

It is crucial to follow up the relevant patents situation, to understand the consequences of this decision on the pharmaceutical market in Brazil. Therefore, Table 3 presents the new situation of molecules patents of relevant drugs that are now subject to a reduction on their former extended terms by the *ex tunc* decision on ADI5529/DF.

Table 3. Patent documents of active ingredients, related to relevant drugs for Brazilian pharmaceutical market; their former expiring dates, due to single paragraph of art.40 provision; their current expiring dates, after ADI5529/DF decision and the correspondent expiring date in USA, their original application country.

Patent number	Tradename (Active ingredient)	Expiring date in US (dd/mm/yy)	Former expiring date (dd/mm/yy)	Current expiring date (dd/mm/yy)
PI9809126-3	ZIAGENAVIR (abacavir sulfate)	14/11/18	06/02/28	14/06/18
PI0012352-8	INLYTA (axitinib)	30/06/20	16/08/26	30/06/20
PI0009721-7	SPRYCEL (dasatinib)	28/06/20	21/11/28	12/04/20
PI9911326-0	HALAVEN (eribulin mesylate)	16/06/19	06/01/25	16/06/19
PI9711437-5	SAXENDA / VICTOZA (liraglutide recombinant)	22/08/22	16/05/27	22/08/17
PI0110955-3	CELSENTRI (maraviroc)	25/05/21	28/06/26	09/05/21
PI0007487-0	STIVARGA (regorafenib)	12/01/20	07/07/25	12/01/20
PI0007487-0	NEXAVAR (sorafenib tosylate)	12/01/20	07/07/25	12/01/20
PI0108394-5	SUTENT (sunitinib malate)	15/02/21	11/12/28	15/01/21
PI9915883-3	BRILINTA (ticagrelor)	02/12/19	18/08/25	02/12/19

DISCUSSION

From Figure 1, molecules and pharmaceutical compositions are the main subject-matter claimed by these extended documents, being 40% and 33%, respectively. Patents whose subject-matter is molecules and pharmaceutical compositions are considered the strongest protection conferred by patens for drugs, since they prevent reproduction of essential characteristics of the products. They prevent, for instance, the use of the active ingredient *per se* (a patent barrier considered insurmountable by any competing drug) or the development of bioequivalent formulations not infringing the patent-protected compositions. They also enable several commercial and strategic practices such as defensive patents, patent fencing, divisional patent applications and continuations, which can be applied to control the domestic market.

Due to that, the fact that the single section of title 40 had been extensively applied in such patents in Brazil, and had benefited such great number of strong patents with longer terms, it is clear that any changes to their terms can severely affect the actual commercial strategies in Brazil.

As shown in Figure 1, columns 1 and 2, 24% of the documents that refer to molecules as subject-matter benefited from 6 to 9 years of term extension, 47% had 1 to 5 years of term extension. Similarly, from patents documents referring to pharmaceutical compositions, 26% benefited from more than 6 years of term extension and 50% were extended by 1 to 5 years.

Column 3 presents the effect the decision on ADI5529/DF had on pharmaceutical patents and it shows that 75% of them were affected by the decision, having their terms immediately shortened. In fact, 73% of patent documents referring to

molecules had their term changed, 88% of the documents referring to pharmaceutical compositions were affected and all patents referring to treatment and combinations (100%) were also affected.

In column 4 of Figure 1, the impact of the decision is presented, considering the current status of the patent documents. It can be observed that only 26% of the documents remained in force after the decision on ADI5529/DF, which means that almost 75% of the patent applications that exert some sort of influence in the pharmaceutical market are extinguished. From columns 3 and 4, 22% of the documents that refer to molecules, 36% of the pharmaceutical compositions patents, 57% of the treatment patents and only one patent on combination remained in force, but they had their term considerably shortened.

If before, approximately 25% of these documents were in force from 2027 to 2031 (Figure 1, column 2), now, the longest-lived patent will expire in 2025, which shows that an unconstitutional 6-year monopoly was conferred by an improper provision of the law.

Column 4 of Figure 1 also shows that 65% of the patent documents expired. 42% (purple flux from column 3 to column 4), however, were in force before ADI5229/DF decision and profiting undue patent term extension. They immediately expired, due to the term correction applied after the *ex tunc* ADI5529/DF decision. Therefore, the actual effect of this decision was that 28% of the 128 patent documents that were in force, had extinguished overnight, greatly influencing the Brazilian pharmaceutical market, since patent exerting exclusivity for a longer period, became immediately subjected to competition.

In addition, column 4 of Figure 1 shows that 7% of the documents were rejected, but remained under appeal even after the decision on ADI5529/DF. Considering the former scenario where single section of title 40 was still applied, if they were granted, they would enjoy 10 years of protection after the patent issuance. Under the single section of title 40 provision, many of those patents, instead of being in force from 20 years from its filling date, they are most likely to be in force from 10 years after granted, if they were granted in a time longer than 10 years after patent filling. Evidently, this scenario results in a completely unpredictable and unfair market. However, after ADI5529/DF decision, the eventual term to be conferred, if granted, will be limited to 20 years from the filing date and no compensation is granted to the applicants who had to deal with delays of more than 10 years in their patens examinations, and with an uncertainty about the merit of their patents.

There are many cases that can be taken as examples of this unprecedented situation. Considering the patent documents PI9915986 (related to a polymorph of everolimus, the active ingredient of Afinitor® - Novartis), and PI0116452 (related to the molecule of pazopanib, active ingredient of Votrient® - Novartis), which were under appeal, by the time of the ADI5529/DF decision. In the former scenario, if the rejected decision they had appealed were reverted, they would be in force, at least, up to 2032! Now, with ADI5529/DF decision determining that the patent-term is fixed in 20 years from filing date, they would be granted already extinct! Cases such those evidence the discrepancies that need to be addressed in the country to fortify its markets, which have to go through strategies of accelerated reviewing, as the single section of title 40 is now unconstitutional and no patents should be in force for a time longer than 20 years after filling.

Furthermore, column 4 of Figure 1 also shows that less than 1% are special cases, in which the effect of the ADI5529/DF *ex tunc* decision was significant to the patent value, as patent application PI0014271-9, referring to the pharmaceutical composition comprising etravirine, (Intelence® (Janssen), an anti-HIV drug, thus relevant to public health policies. Patent was granted in May 20th, 2021, but its 20-year term ended in August, 31st, 2020, being granted already expired. This particular case is an example of a severe delay in examination by INPI. It took to the office 21 years to issue a patent. However, if subjected to the protection conferred by the single section of title 40 as before, it would be in force until May 31st, 2031, which would confer it a 30-year term! It is noteworthy to analyze such situation. In fact, it is unfair to the owner to have a patent which would never be in force, due to examination delays; however, it is equally unfair to profit from a 30-year term, leading to significant uncertainties to the domestic market. Neither case benefits the country with technological development, which should be the main purpose of having patents granted.

Moreover, the *ex tunc* provision may imply in significant financial effects to the owner, which may have developed its research and commercial strategies considering this extended term, especially if it was benefiting from royalties or any other enforcement or negotiation.

Similar effect o commercial strategy affected patent application PI0116266-7, referring to the pharmaceutical composition comprising afatinib, an anticancer drug (Giotrif®-Boehringer Ingelheim). It benefited from the single

section of title 40, having its term extended to October 31st, 2027 and it would still enjoy 4 years of exclusivity. With ADI5529/DF decision, its term was shortened to December 12th, 2021 and enjoyed a remaining term of 7 months instead of 6 years, as it was expected in May, 2021.

It is noteworthy that these patents benefited from term extension conferred by the single section of title 40 of LPI9279/96 because there was a delay in their examination. Therefore, an exclusivity reserve rely on these applications during their examination period, which, in average, is a period of 3 years worldwide, while in Brazil, it took to all documents of interest in this work more than 10 years to reach a decision. As we can see, 7% of the applications were rejected and in face of the examination delay imposed to them, they benefited from an exclusivity reserve they should not, since they were considered unmeritorious at the examination conclusion. Figure 2 presents the term extension expectations on patent applications that were found unmeritorious after examination periods longer than 10 years. Because they were subject to an exclusivity reserve during their examination period, they benefited from a right expectation due to the unpredictability of the examination results. Product developments, commercial and scientific decisions and their commercial value were decided under this long right expectation. From them, 44% had a term extension expectation of more than 9 years (Figure 2).

These delays result in a high legal insecurity that holds back the industrial development and the fair competition. Because of the long period of examination, these documents exert an improper commercial influence for a longer time when they should not, since at the end of the examination process, they were found unmeritorious.

In fact, this analysis evidences the great impact of the decision on the unconstitutionality of the single section of title 40 of LPI9279/96 as being *ex tunc* (will retrogress). Again, as we can see in Figure 3, since this court decision, 75% of the patent documents that benefited from term extension suffered an immediate term reduction, and 38% of these documents with reduced terms were extinct from the decision date. The main effect of the *ex tunc* decision on ADI5529/DF is that these patent applications now have similar terms to their American correspondents, which approximate the interests of industries in Brazilian and foreign pharmaceutical markets.

With the decision on ADI5529/DF, the Brazilian market urges to readapt to the great number of key patents that are no longer in force or had their terms drastically shortened. Actually, the Brazilian industry have been prepared for this decision, since the ADI5529/DF is in discussion since 2016 and now, there is an expectation that it will boost drastic changes on the research and development and commercial strategies of pharmaceutical industry in Brazil, which can boost the generic drugs market and, in the near future, turn an essential generic drugs industry into an innovative one.

The changes promoted by the decision on ADI5529/DF were legally relevant because it took into account the specific scenario occurring in Brazil, in which the Court evaluated the frequent incidence of the single section of title 40 on granted patents by INPI as a tool to correct the effects of the examination delays due to the enormous backlog of patent application examinations by INPI, very difficult to restrain, instead of being an exception rule, turned a patent term undetermined, which goes against free competition.

From Figures 4A and 4B, which present the term extensions of patent applications related to molecules and pharmaceutical compositions before the decision on ADI5529/DF. As previously commented, they show that less than 5% of these documents did not benefit from a significant term extension. It reveals the motivations of pharmaceutical industries to implement irregular strategies to explore INPI backlog. For instance, when INPI examination results in a restriction of the original matter of an application, the applicant accepts the restriction, seeking approval of the original application, but strategically, the applicant files a division of this application containing the same rejected mater to be re-examined in the divided application. Although it is clearly irregular to divide an application, as provided by INPI resolution 124/2013 item 3.136, it is not immediately rejected and it is, in fact, re-examined, which endure its expectation of entitlement. In these cases, the examination is already overdue, and the divided application, by concept, must carry the filing date of the original application. Therefore, the applicant is aware that the divisional application is subject to the provision of the single section of title 40 of LPI9279/96 and of its term extension. It results in a legal uncertainty because an already unmeritorious matter remains in expectation of law, enjoying indirect, extended and indefinite protection until the examination of the divided application is concluded. The decision on ADI5529/DF, therefore, inhibits such irregular practices.

Patent application PI0507007-4, filed in 2005, referring to a pharmaceutical composition exemplifies how damaging this strategy is. This application was found unmeritorious by INPI in

2018 and rejected (note that, even though it was rejected, it enjoyed indirect protection for 13 years, due to rights expectation). The strategy of the applicant (Novartis) to deal with the rejection was to apply 7 divisional documents to review, however the divisional applications were not based on substantial information, but merely proposing alternatives of the same invention. Since then, INPI has been rejecting each of these divided processes, which took the Office until February, 2022 to reject all divisional, due to consecutive appeals, although they were all found illegal.

To understand such impact and inform about the number of patent documents that had their terms extended due to provision of the single section of title 40, it is shown in Figures 4 and 5 that at least 30% of patent applications related to pharmaceutical compositions or molecules had their terms extended to over 6 years, which reveals the significant backlog INPI is dealing with and its influence on the pharmaceutical market.

From Figure 5, molecules and pharmaceutical compositions are 81% of the subject-matter of granted patents. Since these are patents protecting relevant drugs to the Brazilian market, clearly, they exert such a high influence on it, by conferring protection far beyond their already extended terms. These patents already had their terms extended and, by patent management strategies they certainly will be strategically further expanded.

With the *ex tunc* decision on ADI5529/DF, clearly, commercial strategies must be prompt adapted by the Brazilian industry. Because of drugs that are now free to exploitation, the immediate impact could be a price reduction of major drugs. For instance, in the medium term, molecules patents that are now into public domain should be explored for new developments, with massive and more definitive investments in research, aiming new drugs developments by an industry previously focused on the follow-up of patents to expire for the production of similar and generic drugs.

As shown in Table 3 these patents were expect to remain in force in Brazil for several years after their expiration in USA, due to the extension term provisioned by single section of title. 40. However, they immediately expired after the ADI5529/DF decision, which also reduced the discrepancy of patent terms in Brazil and in USA.

It is noteworthy that right after the *ex tunc* decision on the matter by the Brazilian Supreme Court, a great number of lawsuits have been constantly issued, asking for terms reviews to confer extension of the patent terms in force, by supporting the lawsuits on the American provision known as "Patent Term Adjustment (PTA)" not provided in the Brazilian law. It is dangerous to consider that the Court could accept PTA's thesis, because it could lead to a change in the Brazilian Intellectual Property Law, which is not competence of the Judiciary system in the country.

However, while the great number of such lawsuits are being evaluated by the Court, a severe legal uncertainty in the market is increasing, as patents subject-matter that could be in the public domain from 2021, now provide the expectation of a term extension, which, again, inhibit the fair competition and prevent industries to invest in innovation. What is certain is that the pharmaceutical companies found its way to maintain the Brazilian market as uncertain, despite the *ex tunc* decision on ADI 5529/DF.

This is the scenario Brazil is experiencing since May, 2021, when the Court decision in the ADI5529/DF extinguished the single section of title 40 of LPI9279/96, considering it unconstitutional for reasons of preventing the free competition that mainly affected the Brazilian pharmaceutical industry. It is an example of what assuming TRIPS-plus provisions to national laws as a fast way to solve pre-conceived problems may imply in a long term. Due to that lack of vision in predicting the implications of taking a broad decision to solve a specific problem as the term of pharmaceutical patents that entered a new market, such as the Brazilian one in 1996, today the impact of unconstitutionality takes its toll on the pharmaceutical companies, but it can severely damage the Brazilian market. Especially the great number of lawsuits that aim to revert term reductions are providing an uncertain environment for investors of the pharmaceutical sector. Now, it is crucial to follow the next events to evaluate the relevance of such decisions on the future of the Brazilian industry.

CONCLUSION

This work analyzes the immediate effects of the Court decision in the ADI5529/DF, related to the unconstitutionality of the single section of title 40 of LPI9279/96 over US-pharmaceutical patent documents with correspondents in Brazil that benefited from it. It was found that 42% of these patents immediately expired and 26% remained in force in Brazil after the decision, however their terms had been severely shortened (patents that had terms until 2031 will now expire in 2025 at most). This decision immediately changed the Brazilian market and it is expected that, in a medium term, it can be responsible for an industrial strategy change, regarding investments on research and development and may transform an essentially generic and similar drugs industry into an industry

focused on new developments. This work also reveals that an improper monopoly to pharmaceutical companies of more than 6 years was conferred under an unconstitutional provision that, among its harmful effects, had encouraged unfair competition. These effects are expected to be corrected in time with the *ex tunc* decision on ADI5529/DF.

In a broad analysis, this work also evidences that the identification of vulnerabilities in Brazilian industrial property law and possible corrections through new regulations can provide efficient vigilance against irregular and abusive strategies with relevant consequences, such as undue competitive inhibition in sensitive areas such as pharmaceuticals.

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Authors declare there is no conflict of interests involved in this work.

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AUTHOR CONTIBRUTION

TDMEA: data retrieval from patent databases, data organization and treatment, writing and revision.
TDMP: data retrieval from patent databases, data organization and treatment, writing and revision.
TDM: data retrieval from patent databases, data organization and treatment, writing.
DSC: data organization and treatment, writing.

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