INPI issues official report on Ministry of Health priority examination

In July 2019 the National Institute of Industrial Property (INPI) issued an official statistic report on the priority examination of patent applications requested by the Ministry of Health in relation to a number of drugs of interest to the public health policy. The report demonstrates the results of one of the measures adopted by the INPI to speed up the examination of patent applications.

Legal basis for priority examination requests
Under Resolutions INPI/PR 80/2013, 217/2018 and 239/2019, the Ministry of Health can request the priority examination of patent applications related to pharmaceutical processes, products, equipment or health use materials for diagnosis, prophylaxis and the treatment of AIDS, cancer and rare or neglected diseases.

A rare disease is considered to affect up to 65 people per 100,000 individuals (ie, 1.3 people per 2,000 individuals), as defined by the World Health Organisation (WHO).

The following are neglected diseases listed by the Ministry of Health and the WHO:

- chagas disease;
- dengue;
- chikungunya;
- zika;
- schistosomiasis;
- leprosy;
- leishmaniasis;
- malaria;
- tuberculosis;
- buruli ulcer;
- neurocysticercosis;
- echinococcosis;
- bouba;
- paragonimiasis;
- filariasis;
- anger;
- helminthiasis; and
- manifestations resulting from poisoning or poisoning due to poisonous or venomous animals.

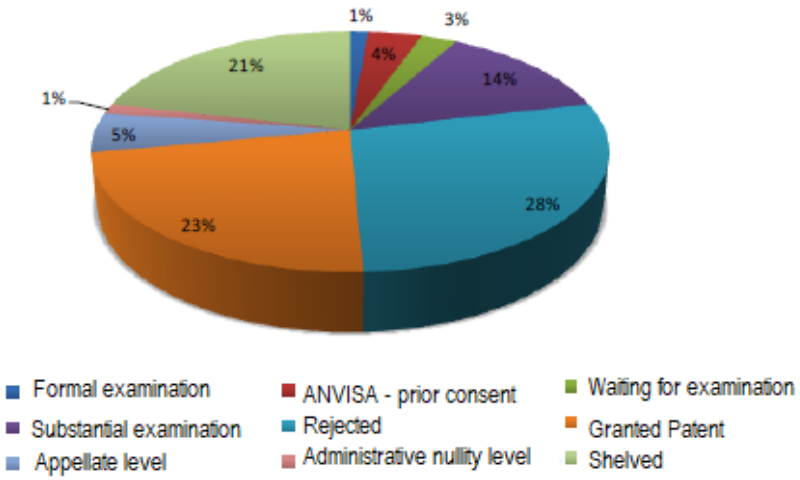
Priority examination is allowed for patent applications related to the Ministry of Health's assistance policies and considered strategic to the scope of the Brazilian healthcare system (SUS).

In order to be eligible for priority examination, a patent application:

- must have been filed before the INPI within the last 18 months or must have had earlier publication requested;
- must have had substantive examination requested; and
- must have not been voluntarily divided or amended by the applicant between the request and the decision regarding priority examination.

Results

Statistics published in the official report show that, in nearly three years, the Ministry of Health submitted 75 priority examination requests to the INPI, of which 79% have already been decided and 21% are still waiting for a decision – as can be seen in the graphic below.



In 2016 the Ministry of Health requested the priority examination of five drugs (Sofosbuvir, Simeprevir, Daclatasvir, Ledipasvir and synthetic phosphoethanolamine). In 2017 the number of requests increased to 15 drugs (eg, Adalimumab, Bevacizumab, Pramipexol, Trastuzumab, Atazanavir, Infliximab, FazaClo) and in 2018 the Ministry of Health also requested the priority examination of Nusinersena (Spunraza)-related patent applications.

Table 1 shows a summary of the results of the INPI's analysis for some of the drugs for which the Ministry of Health requested priority examination.

Table 1

Drug	Number of requests	Number of granted patents	Number of rejected applications	Number of applications waiting examination	Number of shelved applications	Number of applications with substantial examination	Number of applications with ANVISA's prior consent
Sofosbuvir	16	PI0410846-9 (which is now *sub-judice*)	10 (2 under analysis at appellate level)	2	1		
Daclatasvir	9	3 granted patents (PI0716483-1 is under administrative nullity proceeding)	2		3	1	
Simeprevir	11	5 granted patents	2	1	3		

Ledipasvir	4	2 granted patents (PI1010795-9 and BR112014006324-9)			2		
Phosphoethaolamine	2		1 (PI0800463-3)			1	
Adalimumab	8	1 granted patent (PI0512554-5)	1 (PI0415373-1 under analysis at appellate level)		5	1	
Bevacizumab	9	1 granted patent (PI0307702-0)	2 (PI0817182-3) under analysis at appellate level)	1		3	2
Pramipexol	3		2		1		
Everolimus	2	1 granted patent (PI0212922-1)	1 (PI0618808-7)				
Trastuzumab	2		1 (PI0410260-6)			1	

By adopting priority examination measures for pharmaceutical-related patent applications, the INPI has demonstrated not only its intent to reduce the patent backlog, but also its willingness to support the launch of drugs related to public health issues. Further, faster decisions will direct public policies towards partnerships for the local production of strategic generics favouring the SUS's supply (in case of definitively rejected applications).