

INPI prioritises examination of AIDS, cancer, neglected and rare disease-related inventions

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In an attempt to stimulate innovation and address its chronic backlog, the Brazilian National Industrial Property Office (INPI) has expanded its programme to prioritise the examination of patent applications for pharmaceutical products and processes, as well as devices and materials, directly related to the diagnosis, prophylaxis and treatment of certain diseases. The original programme – launched in 2013 – was directed at inventions that addressed AIDS, cancer and other neglected diseases. The latest update, which is set out in Resolution 217, extends the programme to the neglected diseases Zika and Chikungunya, as well as ‘rare diseases’ – defined by the World Health Organisation (WHO) as those affecting 65 out of every 100,000 individuals.

Priority examination may be requested by the Ministry of Health when the subject matter of the application is considered strategic within the scope of the Brazilian Unified Health System, according to a specific list of diseases – or by the applicant or any interested third party. It applies not only to patent applications awaiting first examination but also to those awaiting examination at the appellate level, as well as patents facing administrative nullity proceedings.

In order to be eligible, the patent application:

- must have already been published (or been accepted to national phase if filed via the Patent Cooperation Treaty) with examination already requested;
- must have all annuities duly paid;
- must not have been accepted for any other fast-track examination programme;
- and
- must not have replies pending for office actions.

Neglected diseases in Brazil

Neglected diseases are a diverse group of communicable diseases in roughly 150 countries, mainly in Africa, Asia, Latin America and the Caribbean, which affect more than 1 billion people and cost developing economies billions of dollars every year.

People living in conditions of poverty, without suitable sewage systems and in close contact with infectious vectors, domestic animals and livestock are worst affected. The WHO currently considers 21 diseases as neglected (see Table 1).

Table 1. Current neglected disease portfolio adopted by the WHO

Current neglected disease portfolio adopted by the WHO
Buruli ulcer
Chagas disease
Chicungunya
Dengue
Dracunculiasis (guinea-worm disease)
Echinococcosis
Foodborne trematodiasis
Human African trypanosomiasis (sleeping sickness)
Leishmaniasis
Leprosy (Hansen's disease)
Lymphatic filariasis
Mycetoma, chromoblastomycosis and other deep mycoses
Onchocerciasis (river blindness)
Rabies
Scabies and other ectoparasites
Schistosomiasis
Soil-transmitted helminthiasis
Snakebite envenoming
Taeniasis/Cysticercosis
Trachoma
Yaws (Endemic treponematoses)

Of these diseases, 18 are present in Brazil, with the most common being dengue, Chagas disease, leprosy, leishmaniasis and scabies. In 2019 there have already been 54,777 probable cases of dengue recorded – an increase of 149% over the same period in 2018.

According to Jardel Katz (R&D manager of the Drugs for Neglected Diseases Initiative), “in 2017 Brazil has been responsible for 70% of deaths related to Chagas disease worldwide, 93% of new leprosy cases and 96% of visceral leishmaniasis cases of the continent”.

The WHO’s panel of specialists for the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property recommends that member states spend at least 0.01% of their gross domestic product on R&D for neglected diseases. Brazil currently invests only 0.0004%. This is confirmed by the most recent G-Finder (a project funded by the Bill & Melinda Gates Foundation) report. According to the data in this, Brazilian investments in prophylaxis and control of neglected diseases fell by 42% between 2016 and 2017, to R\$21 million (approximately \$5.5 million).

Neglected diseases – along with AIDS, cancer and rare diseases – represent a significant challenge to Brazilian public health politics, especially given that it is crucial to intensify research efforts due to emerging drug resistance. Such challenges are due to both pharmaceutical companies’ lack of interest in rare and neglected diseases and the high cost of medicines for AIDS and cancer.

Comment

Applying for INPI’s priority examination programme could be helpful, given that its current backlog is between eight and 10 years deep, whereas decisions in other fast-track programmes (such as the Patent Prosecution Highway) take only two years. According to 2018 statistics, the INPI received 52 requests last year, of which 35 have already been granted.