# Canada cannot do enough for USTR and originators

**The US Trade Representative has complied with a request from US brand industry association PhRMA to place Canada on a global intellectual-property Priority Watch List – alongside usual suspects India and China – in its latest 'Special 301' report. David Wallace examines the criticisms.**

After a twelve-month period that has seen Canada row back on its controversial 'promise' doctrine for evaluating the utility of patents, while also introducing two-year patent-term extensions in the form of certificates of supplementary protection (CSPs), the country could have been forgiven for thinking that the criticisms it received last year from the US Trade Representative (USTR) over intellectual-property (IP) might be softened in this year's 'Special 301' report.

However, the opposite has occurred. The USTR has chosen to "downgrade" Canada from the government entity's regular Watch List to its Priority Watch List for "failing to make progress on overcoming important IP enforcement challenges". "Canada remains the only G7 country identified in the Special 301 report," the USTR pointed out, noting that Canada's inclusion reflected "a failure to resolve key longstanding deficiencies in protection and enforcement of IP".

Specifically, the US government's trade body refers to a "weak patent and pricing environment for innovative pharmaceuticals", as well as insisting that the US is "deeply concerned that Canada does not provide customs officials with the ability to inspect, detain, seize and destroy in-transit counterfeit and pirated goods entering Canada destined for the US". But it is Canada's recent Comprehensive Economic and Trade Agreement (CETA) with the European Union (EU) that appears to have been primarily responsible for the USTR's decision to downgrade the country's status.

"With respect to pharmaceuticals, the US has serious concerns about the fairness of Canada's Patented Medicines (Notice of Compliance) – or PM(NOC) – proceedings as amended in September 2017," following the CETA agreement (**Generics *bulletin***, 29 September 2017, page 8), the trade body states.

Moreover, referring to the CSPs that were also prompted by CETA, the USTR says that "Canada's long-anticipated proposal to provide for patent-term restoration for delays in obtaining marketing approval appears to be disappointingly limited in duration, eligibility, and scope of protection".

Pricing issues in Canada are also in the USTR's crosshairs. It complains that changes proposed by Canada's Patented Medicines Prices Review Board (PMPRB) would if finalised "fail to appropriately recognise the value of innovative medicines in both the private and public markets, and would make Canada's pricing policies an outlier among similarly situated countries". Action proposed by the PMPRB late last year aims to curb "excessive prices" for medicines (**Generics *bulletin***, 15 December 2017, page 8).

| Priority Watch List | Watch List | |
|---|---|---|
| Algeria | Barbados | Pakistan |
| Argentina | Bolivia | Peru |
| Canada | Brazil | Romania |
| Chile | Costa Rica | Saudi Arabia |
| China | Dominican Republic | Switzerland |
| Colombia | Ecuador | Tajikistan |
| India | Egypt | Thailand |
| Indonesia | Greece | Turkey |
| Kuwait | Guatemala | Turkmenistan |
| Russia | Jamaica | United Arab Emirates |
| Ukraine | Lebanon | Uzbekistan |
| Venezuela | Mexico | Vietnam |

**Figure 1: The 36 countries on the Priority Watch List and Watch List in the US Trade Representative's 2018 Special 301 report (Source – USTR)**

The USTR's criticisms of the PMPRB closely echo comments made by US brand industry association PhRMA in February, when the association specifically lobbied the USTR to move Canada from the Watch List to the Priority Watch List in this year's report. "Of particular concern are proposed pricing changes for patented products," PhRMA advised the USTR.

However, the USTR was not wholly critical of Canada in its report. Notably, the trade body welcomed the Canadian Supreme Court's decision in mid-2017 to strike down the country's 'promise doctrine' (**Generics *bulletin***, 7 July 2017, page 1), which the USTR referred to as a "restrictive patent utility standard". The trade body had last year railed against the promise doctrine, in line with criticisms previously expressed by PhRMA (**Generics *bulletin***, 2 June 2017, page 14).

Alongside Canada on the USTR's Priority Watch List were regular targets China and India, as well as nine other countries (see Figure 1).

Despite the US and other countries urging China to reform its IP framework, the USTR observed, "results to date have disappointed, as China enacts measures that fail to reflect priority recommendations of the US and others". Revised patent-examination guidelines had not been evenly applied, the report noted, while foreign applicants were disadvantaged compared to local counterparts. Counterfeit pharmaceuticals emanating from China were also a problem, the USTR indicated.

Meanwhile, in India the USTR complained of "narrow patentability standards, the potential threat of compulsory licensing and patent revocations, as well as overly broad criteria for issuing such licences and revocations under the India Patents Act". Furthermore, "costly and time-consuming patent opposition hurdles, long timelines for receiving patents and excessive reporting requirements" were also cited (see Figure 2).

India also "continues to lack an effective system for protecting against the unfair commercial use, as well as the unauthorised disclosure, of undisclosed test or other data generated to obtain marketing approval", the USTR said, with section 3(d) of the India Patents Act restricting eligible subject matter "in a way that poses a major obstacle to innovators seeking timely entry". And India "still lacks an effective system for notifying interested parties of marketing approvals for follow-on pharmaceuticals", the USTR complained, pointing also to pressure to localise product development and manufacturing.

On pharmaceutical counterfeits, the USTR claimed that "India was the origin for 55% of the total value of global counterfeit pharmaceutical seizures", with these medicines "shipped around the globe", particularly to Africa, Europe and the US. Counterfeits were also an issue in Indonesia and Russia, where data-protection issues were also cited. Similar data issues were highlighted in Algeria, Argentina and Chile, as well as regulatory issues in Colombia and the lack of any new patents in Venezuela since 2007. No particular pharmaceutical issues were observed in Ukraine.

Outside of the Priority Watch List, half of the 24 countries on the Watch List also exhibited specific pharmaceutical-related IP issues, according to the USTR (see Figure 3).

Responding to the Special 301 report, international humanitarian body Médecins Sans Frontières (MSF) was highly critical of the USTR's complaints. "At a time when people all over the world are struggling to afford their medicines," MSF said, "it's outrageous that the US government is doing pharma's bidding and bullying other countries into taking actions that would restrict generic competition and limit access to affordable, lifesaving drugs."

"At the urging of pharmaceutical corporations," MSF continued, "the US has used this report to unfairly target countries such as India – known as the 'pharmacy of the developing world' because it supplies affordable generic medicines globally" – as well as other countries such as Colombia "for using legal measures allowed under international trade rules to improve access".

In particular, MSF pointed out that the World Trade Organization's (WTO's) agreement on trade-related aspects of intellectual property rights (TRIPS) permitted the use of compulsory licenses to override patents "to ensure that trade protections do not take precedence over public health needs".

"This report is yet another tactic the US uses to pressure other countries into letting pharmaceutical companies easily attain and hold patents," MSF concluded, "blocking more affordable generic versions of medicines from reaching patients." Instead of "penalising countries like India for trying to care for their citizens", MSF insisted, "the US should instead be taking the opportunity to work with countries to promote measures that get medicines into the hands of the people who need them most".

Conversely, US brand body the Biotechnology Innovation Organization (BIO) praised the USTR's conclusions, but said they should go even further.

BIO welcomed the report's acknowledgement of "the threats that the biopharmaceutical industry faces from a variety of global governmental practices such as abuse of compulsory licensing of IP and reimbursement practices that fail to recognise the value of innovative medicines". But, the association said, the USTR should "more forcefully rebuke the unjustified actions of nations that abuse compulsory licensing".

| | Data protection | Patentability standards | Patent term | Patent backlog | Patent linkage/ prior notice | Pricing & reimbursement | Pro-domestic policies & duties | Counterfeits | Enforcement/ regulation | Compulsory licensing |
|---|---|---|---|---|---|---|---|---|---|---|
| Algeria | X | | | | | | X | | | |
| Argentina | X | X | | X | | | | X | X | |
| Canada | | X | X | | | X | | X | X | |
| Chile | X | | | | X | | | | | |
| China | X | X | | | | | X | X | X | |
| Colombia | | | | | | | | | X | |
| India | X | X | | X | X | | X | X | X | X |
| Indonesia | X | X | | | | | X | X | X | X |
| Kuwait | | | X | | | | | | X | |
| Russia | X | | | | | | | X | X | |
| Ukraine | | | | | | | | | | |
| Venezuela | | | | X | | | | | X | |

**Figure 2: Specific pharmaceutical issues highlighted by the US Trade Representative (USTR) for each of the countries on the Priority Watch List in the USTR's 2018 Special 301 report (Source – USTR/Generics *bulletin*)**

| | Data protection | Patentability standards | Patent term | Patent backlog | Patent linkage/ prior notice | Pricing & reimbursement | Pro-domestic policies & duties | Counterfeits | Enforcement/ regulation | Compulsory licensing |
|---|---|---|---|---|---|---|---|---|---|---|
| Bolivia | | | | | | | | X | X | |
| Brazil | X | | | X | | | | | | |
| Dominican Rep. | X | | | X | | | | X | | |
| Ecuador | | | | | | | | | X | |
| Egypt | X | | | | X | | | | | |
| Guatemala | | | | | | | | X | X | |
| Pakistan | | | | | | | | X | X | |
| Saudi Arabia | X | | | | X | | | | X | |
| Thailand | X | | | X | | | | X | X | |
| Turkey | X | | | | X | X | X | | X | |
| UAE | | X | | | X | | | | | |
| Vietnam | X | | | | | | | X | | |

**Figure 3: Specific pharmaceutical issues highlighted by the US Trade Representative (USTR) for 12 of the 24 countries on the Watch List in the USTR's 2018 Special 301 report. No specific pharmaceutical issues were identified in the other 12 countries (Source – USTR/Generics *bulletin*)**