

SAUDI ARABIA

Saudi Arabia is included in the Watch List in 2018 in response to recent deteriorations in IP protection for pharmaceutical products, in addition to outstanding concerns on enforcement and the continued use of unlicensed software by the government. Saudi Arabia was removed from the Watch List in February 2010 in recognition of the progress to improve its IP regime. However, in recent years, Saudi Arabia has granted marketing approvals to domestic companies to produce generic versions of pharmaceutical products that are under patent protection either in Saudi Arabia or in the GCC. Additionally, these approvals have been granted based on innovators' data that is still covered under Saudi Arabia's system for protecting against the unfair commercial use, as well as the unauthorized disclosure, of undisclosed test or other data generated to obtain marketing approval. These approvals, which may conflict with Saudi Arabia's domestic law, raise significant questions about the transparency of marketing approvals and predictability of patent protection in Saudi Arabia. Additionally, concerns regarding IP enforcement are increasing, including related to difficulty in obtaining information on the status of enforcement actions and investigations, and the lack of seizure and destruction of counterfeit goods. Furthermore, the continued use of unlicensed software by the government, along with the limited number of and training for copyright inspectors, are outstanding concerns. The United States looks forward to continuing to work with Saudi Arabia to address these and other issues.

UNITED ARAB EMIRATES

The United Arab Emirates (UAE) is placed on the Watch List in 2018 in light of longstanding concerns about combatting the sale and transshipment of counterfeit goods and the establishment of collecting management organizations, as well as recent policy changes that may weaken IP protection for pharmaceutical products. While some UAE enforcement authorities seize and destroy counterfeit goods, significant copyright piracy and trademark infringement concerns remain. The 2017 *Notorious Markets List* included two physical marketplaces in the UAE for hosting over 5,000 stores selling a broad range of counterfeit goods, including appliances, communication and acoustic equipment, building materials, machinery, footwear, and designer handbags. In addition to serving purchasers in the UAE, these marketplaces also operate as gateways to distribute counterfeit goods to other markets in the region, North Africa, and Europe. Additionally, the lack of IP enforcement actions within FTZs is a concern. For instance, rather than seizing and destroying counterfeit goods in FTZs, UAE officials reportedly allow the re-export and transshipment of such products, despite having the authority for the destruction of counterfeit goods. U.S. right holders also continue to raise concerns over the lack of IP prosecutions; a lack of permanent staff solely dedicated to counterfeit enforcement; a lack of enforcement action without specific, written complaints from right holders; and a lack of transparency and available information related to raids and seizures of pirated and counterfeit goods. Moreover, despite repeated requests by the United States and right holders and the existence of implementing regulations, the UAE has yet to grant the necessary operating licenses to establish CMOs to allow copyright licensing and royalty payments. Stakeholders also raise concerns over the high trademark filing fees in UAE, which are the highest in the world and considered cost-prohibitive to protecting trademarks in the UAE. Furthermore, in April 2017, UAE officials allowed domestic manufacture of generic versions of pharmaceutical products still under patent protection in the United States. The UAE claimed that previous measures providing

country of origin patent protection for pharmaceutical products – the Decree 404 system – were no longer valid. The Decree 404 system provides important protections for innovative products that are not otherwise available through other mechanisms in the UAE’s intellectual property and regulatory systems. It is also unclear whether the UAE intends to continue to recognize patents granted by the GCC Patent Office. These actions demonstrate a lack of predictability and transparency that has created a sense of instability and confusion amongst stakeholders in the innovative pharmaceutical industry. The United States looks forward to continuing to work with UAE to address these and other issues.