

### *Inside this Issue*

---

*FDA Finalizes 46 Bioequivalence Guidance* **2**

---

*GCC Trademark Law Comes into Force in Oman* **2**

---

*Draft Intellectual Property Policy of the Republic of South Africa* **3**

---

*Speedy Trade Mark Registration: Controller's Public Notice to file Examination* **3**

---

*EPO releases unitary patent guidelines* **4**

---

*Behind the Scenes: the making of the 2017 CRI Guidelines* **4**

---

*Union Cabinet clears India, Sweden MoU signing on intellectual property right* **5**

## 1. FDA Finalizes 46 Bioequivalence Guidance

**THE US FOOD AND  
DRUG  
ADMINISTRATION  
FINALIZED SEVERAL  
GUIDANCE'S TO  
ANALYSIS, MEASURE  
AND TESTING METHODS  
FOR A PARTICULAR  
GENERIC DRUG.**

*In its continued push to support the development of generic drugs, the US Food and Drug Administration (FDA) on Friday finalized 46 product-specific bioequivalence guidance's. The guidance's, which lay out FDA's expectations for the studies that should be done to demonstrate that a generic drug is bioequivalent to its reference product, give specific recommendations for what analyses to measure, what dissolution test methods and sampling times. Some of the guidance's also specify the testing that can be done in order to obtain a waiver for in vivo testing, though for some products, such as valporic acid, FDA says in vivo tests should be done. [Read more](#)*

## 2. GCC Trademark Law Comes into Force in Oman

**GCC TRADEMARK LAW  
HAS ARTICLES, RULES,  
OUTLINES THAT  
ENABLES,  
REGISTRATION,  
RENEWAL AND  
CANCELLATION  
PROCEDURES.**

*MUSCAT - Oman adopted the GCC Trademark Law that came into force in the country as of July 25, 2017. The GCC Trademark Law, which was published in the Official Gazette No. 1204, comprises 52 articles, and outlines the general directives and rulings governing trademark registration, renewal, and assignment and cancellation procedures in the GCC countries. Although the GCC Trademark Law has been adopted in Oman, the Implementing Regulations of the law and the related fees have not yet been released. For further details and inquiries on the GCC Trademark Law, please contact AGIP office in Oman at: [oman@agip.com](mailto:oman@agip.com) [Read more](#)*

## 3. Draft Intellectual Property Policy of the Republic of South Africa

### **DRAFT POLICY FOR ACHIEVING BALANCED AND COORDINATED IP SYSTEM IN SOUTH AFRICA**

*South Africa's Department of Trade and Industry has released Draft Intellectual Property Policy (Phase I). The full document is here (PDF). The introduction, which summarizes the policy's goals and proposed reforms, is below.*

*The National Development Plan (NDP) of South Africa calls for a greater emphasis on innovation, improved productivity, an intensive pursuit of a knowledge economy and the better exploitation of comparative and competitive advantages. [Read more](#)*

## 4. Speedy Trade Mark Registration: Controller's Public Notice to file Examination Reports

### **TRADEMARK APPLICANTS ASKED TO RESPOND ON EXAMINATIONS THAT WERE SENT BEFORE 15TH SEPTEMBER, 2017**

*On 14th August, 2017, in an attempt to speeden the trade mark registration process and clear the back log, the Controller of Patents, Designs and Trade Marks issued a public notice asking applicants to respond to examinations that were sent by the Trade Mark Registry before 15th September, 2017. As per the notice, not filing a response before the said date will result in abandonment of the trade mark application. A list of trade marks for which examination reports have been sent has been published by the trade mark registry, and applicants, and/or their trade mark attorneys, can search if their trademarks are among the listed applications. [Read more](#)*

## 5. EPO releases unitary patent guidelines

**NEW PATENT  
GUIDELINES  
RELEASED ,WHICH  
ENABLES TO  
REDUCE THE COST OF  
RENEWAL FEES.**

*The European Patent Office (EPO) has released a new guide on securing unitary patent protection.*

*The EPO's guide stresses the cost effectiveness of unitary protection, with the new form of patent incurring significantly less cost than national routes. Total renewal fees for the first 10 years—the average lifetime of a patent, according to the EPO—would amount to less than €5,000. A full 20-year patent would cost its owner nearly €36,000 in renewal fees. [Read more](#)*

## 6. Behind the Scenes: the making of the 2017 CRI Guidelines

**REVISED  
EXAMINATION  
GUIDELINES FOR THE  
COMPUTER  
RELATED INVENTIONS  
(CRI)  
HAVE BEEN RELEASED**

*In July this year, we covered the Indian Patent Office's decision to revise its examination guidelines for Computer Related Inventions ("CRI Guidelines"). We noted that it was the third set of guidelines released in as many years – the guidelines were first issued in August 2015, suspended and kept in abeyance until February 2016, when a fresh set was issued which almost entirely contradicted its predecessor.*

*We have dealt with the substance of the guidelines earlier – the 2015 Guidelines were seen as broadly opening the gates for software claims, while the 2016 Guidelines introduced fresh provisions in Paragraphs 5 and 6 which were perceived to preclude all software claims from patent protection. [Read more](#)*

## 7. Union Cabinet clears India, Sweden MoU signing on intellectual property right

**MOU HAS BEEN SIGNED  
BETWEEN INDIA AND  
SWEDEN FOR WORKING  
TOGETHER REGARDING  
INTELLECTUAL  
PROPERTY  
TO RAISE AWARENESS  
ON IPR, THROUGH  
VARIOUS TRAINING  
PROGRAMMES**

*The Union Cabinet today cleared MoU signing between India and Sweden on intellectual property right (IPR) cooperation, aimed at benefiting entrepreneurs, investors and businesses.*

*The Cabinet meeting, chaired by Prime Minister Narendra Modi, approved the memorandum of understanding (MoU), an official statement said. This will enable India to exchange experiences in innovation and IP ecosystems.*

*"The MoU establishes a wide-ranging and flexible mechanism through which both countries can exchange best practices and work together on training programmes and technical exchanges to raise awareness on IPRs and better protect intellectual property rights," the statement read.*

*The government hopes that the MoU signing will further the objective of National IPR Policy, 2016, and sees it as a landmark step towards becoming a major player in global innovation.*

[Read more](#)