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## 1. EU looks to new patent guidelines

**EU'S PLANS INCLUDE AN EXAMINATION OF LICENSING PRACTICES AND INTELLECTUAL PROPERTY VALUATION. THE COMMISSION IS ALSO LOOKING AT EVALUATING WHICH PATENTS.**

*The European Commission is set to step into the row of patents, an issue that has poisoned many business relationships and provoked a flurry of lawsuits. According to a report from Reuters, the Commission has published a set of guidelines in an attempt to strike a balance between patent holders and their users. The last year alone has seen a collection of disputes, notably, in the mobile phone arena, between Apple and Qualcomm.*

*The European guidelines have acceded to some of the patent holders' demands, for example, by no longer requiring patent owners to provide licenses to all.*

[Read more](#)

## 2. Taiwan, UK sign MOU on biological material patent applications

**TAIWANESE AND U.K. DELEGATIONS ADDRESSED ISSUES MEASURES TO COMBAT COPYRIGHT INFRINGEMENT ONLINE, IMPROVE THE QUALITY OF PATENT REVIEWS.**

*Taiwan and the United Kingdom signed a memorandum of understanding (MOU) during their 20th round of trade talks in London Dec. 1 to facilitate the process of filing patent applications involving biological material. According to a Saturday press statement from Taiwan's Intellectual Property Office (IPO), the MOU was signed between the IPOs of the two countries because of the increasing number of patent applications coming from the U.K. in the biomedical sciences field that involve biological material.*

*Currently, Article 27 of Taiwan's Patent Act reads: "When filing a patent application for invention involving a biological material .*

[Read more](#)

## 3.USPTO unveils new filing system

**THE NEW SYSTEM WILL  
RUN IN BETA  
THROUGHOUT 2018,  
WITH THE AIM TO  
COMPLETE A FULL  
TRANSITION BY 2019.**

*The US Patent and Trademark Office (USPTO) has unveiled a new filing system that will launch in 2018 and be fully implemented by 2019.*

*In a blog post on the USPTO website, commissioner for patents, Drew Hirshfield, explained that the new system, Patent Center, will replace the current EFS-Web and PAIR systems and aim to be more user friendly, allowing applicants to file and view their patent applications in one central location.*

*Patent Center will include new features, including the ability to upload multiple documents at a time, drag-and-drop documents, and save submissions.*

[Read more](#)

## 4.Changes in Patent Language to Ensure Eligibility Under Alice

**PROPOSED STRATEGY  
FOR ENSURING  
ELIGIBILITY UNDER THE  
ALICE TEST IS TO AVOID  
CLASSIFICATION INTO  
TECHNOLOGY CENTER  
3600 AND/OR CLASS 705.**

*When a rule becomes a target, it ceases to be a good rule. In the three years since the Supreme Court issued its opinion in Alice, there have been positive changes to patent applications, but there remains a long-term risk that patent practitioners will use tricks to beat the Alice test. Here, we focus on the changes to patent applications by drafters, as well as changes to patent applications that have issued since Alice.*

*In Alice v. CLS Bank, the Supreme Court laid down a straightforward, if difficult to consistently apply, test for patent eligibility under 35 U.S.C. § 101. Patent eligibility is to be determined based on 1) whether the claims at issue are directed to a patent-ineligible concept; and 2) if so, whether the claim's elements, considered both individually. [Read more](#)*

## 5. FDA Issues Fourth and Final Software as a Medical Device Clinical Evaluation Guidance

**GUIDANCE FOCUSES ON PRINCIPLES CLINICAL EVALUATION: VALID CLINICAL ASSOCIATION, ANALYTICAL VALIDATION, CLINICAL VALIDATION.**

*The FDA recently released "Software as a Medical Device (SaMD): Clinical Evaluation," a final guidance document that aims to establish a common understanding of clinical evaluation and principles for demonstrating the safety, effectiveness and performance of Software as a Medical Device. Rather than replace or conflict with existing regulatory requirements or provide recommendations for application to specific situations, the guidance provides an evidentiary and technical framework to evaluate safety and performance of SaMDs throughout the product's lifecycle.*

[Read more](#)

## 6. WIPO Stats on Patent Application Filings Shows China Continuing to Lead the World

**STATISTICS REFLECT HOW CHINESE FEDERAL GOVERNMENT HAS BEEN WORKING TO CREATE INCENTIVES TO INNOVATE AND GET CHINESE INNOVATORS TO FILE MORE PATENT APPLICATIONS.**

*The World Intellectual Property Organization (WIPO) released statistics on worldwide filing activities for patent, trademark and industrial design applications for 2016. One clear take away from the data released by WIPO is the growing dominance of China as a forum for patent application filings, underscoring the growing dichotomy of current patent policy regimes between China and the U.S. and how well either country is incentivizing innovation.*

*Globally, a total of 3.1 million patent applications were filed with patent offices worldwide during 2016, an increase of 8.3 percent over 2015's filing numbers and the seventh straight year in which saw a year-over-year increase in global patent application filings.*

[Read more](#)

## 7. Use of Standards at CBER: New Draft Guidance

**STANDARDS  
DEVELOPMENT AND THE  
USE OF STANDARDS IN  
REGULATORY SUBMIS-  
SIONS REVIEWED IN THE  
CENTER FOR BIOLOGICS  
EVALUATION AND RE-  
SEARCH.**

*The US Food and Drug Administration's (FDA) Center for Biologics Evaluation and Research (CBER) on Monday released draft guidance offering recommendations on the use of standards in product development and the use of such standards in CBER's managed review process.*

*The draft describes how standards are developed, the benefits of using standards and CBER's policy on accepting standards used in regulatory submissions. Questions and answers contained within the draft range from the basics ("What is a Standard?" and "How do Standards Differ from Regulations?").*

[Read more](#)

## 8. EPO extends fast-track pilot programmes with four countries

**EPO HAS OPERATIONAL  
PPH PILOT PRO-  
GRAMMES WITH THE IP5  
OFFICES (THE GROUPING  
OF THE WORLD'S FIVE  
LARGEST IP OFFICES,  
MADE UP OF THE EPO  
AND THE PATENT OF-  
FICES OF CHINA, JAPAN,  
KOREA, AND THE US).**

*With effect from 6 January 2018, the EPO will be extending its PPH pilot programmes with four partners around the globe, namely Canada, Israel, Mexico and Singapore, thus enabling innovators from Europe and these countries to continue obtaining patents more quickly and efficiently. All four PPH pilot programmes are being extended for three years until 5 January 2021, and the current conditions and requirements for participation will continue to apply.*

*The trials with Canada, Mexico and Singapore stem from bilateral agreements which EPO President Benoît Battistelli signed with the respective heads of patent offices at the side lines of the 2014 World Intellectual Property Organization General Assembly in Geneva. [Read more](#)*

## 9. EUIPO Notice on Brexit

**THOSE UNABLE TO DO UK AND EU REGISTRATIONS, IT IS HOPED THAT EU RIGHT-HOLDERS WILL ENJOY PROTECTION IN THE UK WITH A NEW EQUIVALENT UK NATIONAL RIGHT.**

*The European Commission issued a notice, countersigned by the EUIPO, to right-holders of and applicants for EU trade marks (EUTMs) and Registered Community Designs (RCDs), looking at the potential scenario in which no agreement is reached between the UK and the remaining 27 EU Member States in the Brexit negotiations. In the notice, it is stated that, unless a ratified withdrawal agreement establishes another withdrawal date or the period is extended, on 30th March 2019 the UK will become a "third country", i.e. it will no longer be an EU Member State. Any EUTM or RCD rights granted by the EUIPO on or after the withdrawal date will only be valid in the 27 EU Member States.*

[Read more](#)

## 10. FDA Finalizes Guidance on Promotional Drug Labeling and Ads

**HELPS IN RECOGNIZING CLAIMS IN PRESCRIPTION DRUG PROMOTION THAT HAVE THE POTENTIAL TO DECEIVE OR MISLEAD CONSUMERS AND HEALTH CARE PROFESSIONALS .**

*The US Food and Drug Administration (FDA) on Monday finalized guidance from 2013 on prescription drug product name placement, size, prominence and frequency in promotional labeling and advertisements for human prescription drugs.*

*FDA said it received one comment on the revised draft guidance, and in addition to a title change and editorial changes made primarily for clarification, the guidance has been revised to clarify certain concepts discussed in the revised draft guidance and to provide examples illustrating prominence issues. FDA further clarifies issues relating to the direct conjunction of the proprietary and established names.*

[Read more](#)

## 11. Iraq: Updated Trademark Registration System

**IRAQI TM OFFICE  
SUSPENDED ALL APPLI-  
CATION THAT ARE FILED  
UNDER OLD SYSTEM  
AND SUGGESTED TO  
REFILE ALL THOSE APPLI-  
CATION WITH NEW  
APPLICATION FILING  
SYTEM.**

*The Iraqi Trademark Office suspended all pending applications with filing numbers ranging between 50,000 and 72,000, given that these applications were filed under the old system. Applicants therefore must re-file their applications under the new system at the TMO. Additionally, renewals and changes of name and/or address cannot be filed if the trademark is not registered.*

*This news follows the introduction of a new procedure at the TMO for the renewal of trademarks, and for the recordals of assignment, merger, change of name, as well as change of address. This procedure would entail the publication of notices in the Official Gazette. [Read more](#)*

## 12. New nonmaterial could enable new types of chemical processes in pharma, materials and chemical industries

**NEW MATERIAL ALLOWS  
PRECISE CONTROL OF  
'HOT ELECTRONS' USING  
QUANTUM EFFECTS,  
OPENING NEW AVENUES  
IN CHEMICAL RESEARCH.  
METAMATERIAL ALSO  
HAS USES AS A HIGHLY  
SENSITIVE GAS SENSOR.**

*Scientists at King's College London have engineered a new nano-scale device which creates a controlled stream of 'hot electrons' - high energy electrons which allow unusual chemical reactions to take place. This could open up new research avenues for pharma, chemicals and materials industries.*

*The research, published in Nature Nanotechnology on 11 December 2017, describes how a metamaterial - a material with properties not found in nature - can be constructed which uses quantum effects to turn electrons flowing through a circuit into hot electrons and light, in a highly controlled manner. [Read more](#)*