HASAN AND SINGH
Intellectuals @ Law
Advocates, Patent And Trademark Attorneys

NEWSLETTER
FEBRUARY 2017

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1. NASA, AIPLA, IPO among those who oppose USPTO fee increases

ACCORDING TO THE USPTO, THE FEE INCREASES ARE DESIGNED TO BETTER COVER THE COSTS OF THE USPTO'S MAIN PATENT OPERATIONS

On October 3rd, the Federal Register printed a notice of proposed rulemaking from the U.S. Patent and Trademark Office regarding increased fees for patent application filings and petitions filed with the Patent Trial and Appeal Board (PTAB). As proposed, the rules would increase fees for filing, search and examination on both design and utility patent applications by at most $140. Much larger increases were seen for filing petitions with PTAB for inter parties review (IPR), covered business method (CBM) and post-grant review (PGR) proceedings, such as an increase of $5,000 for IPR petitions seeking to challenge the validity of up to 20 claims.

According to the USPTO, the fee increases are designed to better cover the costs of the USPTO's main patent operations as well as PTAB operations and administrative services. [Read more]

2. Biotech firms form patent alliance over interference proceeding against CRISPR Patent application

THE ALLIANCE IS COMPOSED OF FIRMS THAT HAVE A VESTED INTEREST IN THE OUTCOMES OF A CRISPR PATENT INTERFERENCE CASE

In mid-December, medical and business news outlets alike were reporting on the formation of a patent licensing alliance among biotech firms and a leading research university. The alliance is composed of firms that have a vested interest in the outcomes of a CRISPR patent interference case currently in front of the U.S. Patent and Trademark Office's Patent Trial and Appeal Board (PTAB). The interference proceeding specifically involves patents covering CRISPR/Cas9 gene editing technologies. The companies joining the alliance include Ireland-based ERS Genomics and Switzerland's CRISPR Therapeutics. [Read more]

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3. Good news for patent applicants – validation in Europe just got cheaper

NO LONGER NECESSARY TO PROVIDE A TRANSLATION OF A EUROPEAN PATENT FOR IT TO TAKE EFFECT IN BELGIUM

From 1 January 2017, Belgium has relaxed the requirements for validating a granted European patent – it is no longer necessary to provide a translation of a European patent for it to take effect in Belgium. Since translations have always been one of the more expensive aspects of securing patent protection in Europe, this can only be a good thing.

Belgium is only a small country but it is relatively wealthy, with a GDP just outside the top ten of European countries. [*Read more*]

4. Healthcare sector needs rational stent pricing: NATHEALTH

THE GOVERNMENT NEEDS TO FORM A HEALTH TECHNOLOGY ASSESSMENT BOARD FOR STANDARDIZING AND REGULATING THE STENT QUALITY IN INDIA

In view of recent government notification to bring stents under drug price control order and its implications on healthcare technology providers, Healthcare Federation of India (NATHEALTH) has suggested that the government needs to form a Health Technology Assessment Board for standardizing and regulating the stent quality in India.

Medical procedures in India are among the most affordable in the world, which is a combination of cost of devices and services. Any notification should be considered only if it can bring down the overall cost of treatment for the patient without denying them the options to avail the treatment of their choice. Additionally, such notifications significantly impact the 'Make in India' attractiveness of the country, said Rahul Khosla, president, NATHEALTH. With recent government notification to bring stents under the country's drug price control order. [*Read more*]

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5. Indian companies grab 34% of total US FDA approvals during 2016

THE INVESTMENTS IN R&D ACTIVITIES HELPED THEM TO SECURE HIGHER NUMBER OF APPROVALS FROM REGULATORY BODIES IN THE WORLD

Indian pharmaceutical companies have registered strong presence in highly regulated markets like US and Europe with rising investment in research and development (R&D) activities during last couple of years. The Investments in R&D activities helped them to secure higher number of approvals from regulatory bodies in the world. During the year 2016, Indian companies secured highest number of approvals during last decade. Indian companies received approval for 201 Abbreviated New Drug Application (ANDA) from the United States Food and Drug Administration (FDA) out of total 598 ANDA approvals. Read more

6. US FDA issues new guidelines for safety testing of drug metabolites

GENERALLY, METABOLITES IDENTIFIED ONLY IN HUMAN PLASMA AT DISPROPORTIONATELY HIGHER LEVELS IN HUMANS THAN IN ANY OF THE ANIMAL TEST SPECIES SHOULD BE CONSIDERED FOR SAFETY ASSESSMENT

US FDA has issued Safety Testing of Drug Metabolites guidance for the pharma and biotech industry. The new norms provide recommendations to industry on when and how to identify and characterize drug metabolites whose nonclinical toxicity needs to be evaluated.

The safety of drug metabolites may need to be determined in nonclinical studies because these metabolites are either identified only in humans or are present at disproportionately higher levels in humans than in any of the animal species used during standard nonclinical toxicology testing. The guidance applies to small molecule non biologic drug products. It does not apply to some cancer therapies where a risk-benefit assessment is considered. Read more

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7. Pharma & healthcare sectors see R&D, manufacture & predictive analytics as growth drivers in 2017

INDIA PHARMA CONTINUES TO RIDE THE WAVE WITH ROBUST DOUBLE DIGIT GROWTH IN SPITE OF ALL THE CHALLENGES THEY FACED IN THE YEAR

Indian pharma companies will prove its mettle in R&D and manufacture in 2017. The sector's capability holds immense potential in contract research and clinical trial segments. In the healthcare space, IoT (Internet of Things), wearable technology and remote healthcare programmes, besides predictive analytics can be used to devise a plan for personalized care where the patients can choose to customize all aspects of their healthcare. From a government perspective, there is need for a slew of initiatives like dedicated medical device regulation, Goods and Services Tax (GST), handling the issue of Fixed Dose Combinations (FDCs) at a faster pace. [Read more]

8. FDA finalizes guidance on clinical Pharmacology data to support Biosimilars

CLINICAL PHARMACOLOGY STUDIES ARE PART OF A STEPWISE APPROACH FOR DEVELOPING THE DATA AND INFORMATION NEEDED TO SUPPORT BIOSIMILARITY STUDIES

Between Christmas and the beginning of 2017, the US Food and Drug Administration (FDA) finalized guidance from 2014 to help biosimilar sponsors understand what clinical pharmacology data is necessary to support a proposed biosimilar.

The 18-page guidance is one in a series implementing the Biologics Price Competition and Innovation Act of 2009 (BPCIA) that established a pathway for the approval of such follow-on biologics. Four other final guidance documents and two other draft guidances have been released by FDA so far and guidance on interchangeability is expected this year (to read more about biosimilars see the Focus explainer from last year). [Read more]

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9. UN Establishes Technology Bank for Least-Developed Countries, Including an IP Bank

IT WILL BE FINANCED BY VOLUNTARY CONTRIBUTIONS FROM MEMBER STATES AND OTHER STAKEHOLDERS

The United Nations has established a "technology bank" for least-developed countries that aims to strengthen the science, technology and innovation capacity of LDCs that includes better management of intellectual property rights.

A resolution establishing the UN Technology Bank for the Least Developed Countries was passed by the UN General Assembly on 23 December.

The Technology Bank website is here. The press release on the Bank is here. The General Assembly Resolution A/71/L.52 is here. The 3-year strategic plan is here. Read more

10. ARIPO Amends Protocol on Patents, Utility Models and Designs

CURRENTLY, THE PROTOCOL IS IN FORCE IN ALL THE ORGANISATION'S 19 MEMBER STATES EXCEPT SOMALIA

The Harare Protocol on Patents, Industrial Designs and Utility Models has been amended. The amendments were adopted by the 40th Session of the African Regional Intellectual Property Organization (ARIPO) Administrative Council, and came into operational effect from 1 January 2017.

ARIPO's Administrative Council held a meeting from 5-7 December in Harare, Zimbabwe. The Administrative Council is composed of heads of offices responsible for industrial property and copyright in member states.

The Harare Protocol empowers ARIPO to grant patents and register industrial designs as well as utility models on behalf of the contracting states. The protocol was first adopted in December 1982 and came into force in April 1984. Read more

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11. USPTO announces new Patent and Trademark Advisory Committee Members

EACH COMMITTEE HAS NINE VOTING MEMBERS WHO ARE APPOINTED BY, AND SERVE AT THE PLEASURE OF, THE SECRETARY OF COMMERCE.

The U.S. Department of Commerce's United States Patent and Trademark Office (USPTO) announced new Patent and Trademark Advisory Committee Members for the Patent Public Advisory Committee (PPAC) and the Trademark Public Advisory Committee (TPAC).

The Public Advisory Committees for the USPTO were created through the Patent and Trademark Office Efficiency Act statute in the American Inventors Protection Act of 1999 to advise the Secretary of Commerce and the Under Secretary of Commerce for Intellectual Property and Director of the USPTO on the management of patent and trademark operations. Read more

12. Unified Patent Court will become operational in December 2017

THE TIMETABLE IS CONDITIONAL AND PROVIDED WITH THE CLEAR DISCLAIMER THAT THERE ARE A NUMBER OF FACTORS THAT WILL DICTATE WHETHER IT IS ACHIEVABLE

The Preparatory Committee for the Unified Patent Court (UPC) expects the court to become operational in December of this year, with the Provisional Application Phase (PAP) starting by the end of spring 2017, probably in May.

According to the announcement, 'the start of the sunrise-period for the possibility to opt out European patents is now planned for early September 2017 which will provide a minimum of 3 months for patent holders who wish to opt out their patents to do so before the Court becomes operational.' The Preparatory Committee stresses: 'The above timetable is conditional and provided with the clear disclaimer that there are a number of factors. Read more

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13. Turkey: New IP Law Trademarks – Geographical Indications Prosecution & Enforcement

COLORS AND SOUND MARKS HAVE BEEN INCLUDED IN THE DEFINITION OF SIGNS WHICH MAY BE PROTECTED AS A TRADEMARK

The new Law entered into force upon being published in the Official Gazette of January 10, 2017. Here are some major changes introduced by the new Law.

Colors and sound marks have been included in the definition of signs which may be protected as a trademark. More importantly, the requirement of capability to be represented graphically and reproduced by printing is removed in view of existing electronic means, in order to pave the way for motion marks.

Trademark applications consisting solely of or identically comprising the registered geographical indication will be rejected on absolute grounds at the examination. [Read more]

14. Trademark fee changes (USPTO)

THESE CHANGES ARE MADE FOR MORE EFFICIENT RESOLUTION OF APPEALS AND TRIALS, AND TO PROMOTE THE EFFICIENCY OF THE TRADEMARK PROCESS

We are changing some trademark processing and service fees effective Jan. 14, 2017. Make sure you pay the correct amount, especially if you are not paying online.

All fees paid for paper filings will increase. The per-class fee for an initial application for registration filed on paper is going from $375 to $600. Fees are increasing anywhere from $75 to $200 (per class, where applicable) for paper filings.

The per-class fee for an initial application for registration filed using the regular Trademark Electronic Application System (TEAS) option will increase by $75 to $400. This increase also applies to requests for extension of protection and subsequent designations filed under the Madrid Protocol. 15 U.S.C. 1141e; Madrid Protocol Article 8(7)(a). [Read more]

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15. Punitive damages for IP infringements can be provided for by EU countries, rules EU court

Businesses that infringe the intellectual property (IP) rights of others can be ordered to pay damages that value multiple what it would have cost them to licence the use of that IP legitimately, the EU's highest court has said.

The Court of Justice of the EU (CJEU) said EU law does not preclude EU countries from drawing up national legislation that provides for punitive damages to be awarded to rights holders where their IP has been infringed. The CJEU was asked to rule on the issue by a court in Poland which had raised a question over how the EU's directive on enforcement of IP rights should be interpreted. he issue is pertinent to a dispute before the Polish court between a copyright licensing body and cable TV broadcaster in the country. The directive on enforcement of IP rights requires each EU member state to implement "the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights". The measures, procedures and remedies introduced must be "fair and equitable" and not be "unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays", but must be "effective, proportionate and dissuasive and ... be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse". On the issue of damages specifically, the directive requires each EU country to ensure that courts, when assessing claims for damages for IP infringement, "order the infringer who knowingly, or with reasonable grounds to know. Read more

ACCORDING TO THE DIRECTIVE, THERE ARE TWO APPROACHES COURTS CAN TAKE WHEN SETTING DAMAGES FOR IP INFRINGEMENT

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