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

NEWSLETTER
JULY 2016

Inside this Issue

Court decides that ANDA approved before Patent issued cannot infringe 35 U.S.C. § 271 (e)(2)(A)	2
IBM has been awarded an average of 24 patents per day so far in 2016	2
WIPO members agree new text on IP and genetic resources; move talks forward	3
New ideas coming for WTO TRIPS Council; but also old debate over EU drug seizures	3
If India signs RCEP, it will not be the 'pharmacy of the world': MSF	4
UN Development Agency issues guidelines for pharmaceutical Patent examiners	4
US Supreme Court lowers bar to larger Patent damage awards	5
Govt issues Patent guidelines for Indian Startups; facilitator must for filing Patents	5
Intellectual Property Court established in Ukraine	6
Patent office caps fast-track requests	6
Biotech, devices cos should take advantage of Govt's 'ease of doing business' & IPR policy to step up making critical components: DBT secretary	7
"We are seeing increasing use of our systems by Indian enterprises"	7
Government permits 74 % FDI under automatic route for brownfield pharmaceuticals	8
Heading for Brexit: Will United Kingdom's intellectual property protections Brexit too?	8

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1. Court Decides that ANDA approved before Patent issued cannot infringe 35 U.S.C. § 271(e)(2)(A)

MAKE SURE YOUR PATENT ISSUES PREFERABLY BEFORE ANY ANDA IS FILED.

Although the Hatch-Waxman Act was passed by Congress decades ago, it still produces new questions. Despite vigorous argument by the patent owner, a district court dismissed a count alleging that the ANDA-filer infringed under 35 U.S.C. § 271(e)(2)(A), leaving in place the unchallenged count for infringement under § 271 (a). Ferring B.V. v. Actavis, Inc., Civil Action No. 15-4222 (D.N.J. May 26, 2016).

The FDA approved Ferring's NDA for tranexamic acid formulations on November 13, 2009. Defendant Watson Laboratories filed its Abbreviated New Drug Application (ANDA) on July 23, 2010, seeking FDA approval to market generic tranexamic acid. Read more

2. IBM has been awarded an average of 24 patents per day so far in 2016

IBM ACCOUNTED FOR ABOUT 1% OF ALL US PATENTS AWARDED IN 2015

The media tends to focus on the crazy things Google, Facebook, and Apple patent, but they're still dwarfed by more traditional companies like IBM and Samsung when it comes to the number of patents they're awarded each year. Through the first half of 2016, IBM has, yet again, been the leader in technology patents, averaging roughly 23.6 patents awarded each day.

Although IBM's patent-producing power slowed somewhat in 2015, the number of patents it's received so far this year is up more than 13% compared to a year earlier. The company is in the middle of a painful reinvention, that sees the company shifting further away from hardware sales into cloud computing, analytics, and AI services. Read more

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3. WIPO members agree new text on IP and genetic resources; move talks forward

MEMBERS AGREE NEW TEXT ON IP AND GENETIC RESOURCES

World Intellectual Property Organization members negotiating for an instrument to protect against theft of genetic resources last week agreed on a new text with more options on legal terms, effectively moving the talks forward. In this round of talks, the African Group showed signs of moving off its position of revoking patents for violators, while the United States came out strongly against disclosure of origin at the expense of amiable relations with key allies. *Read more*

4. New ideas coming for WTO TRIPS Council; but also old debate over EU drug seizures

THE NEW EU TRADEMARK LAW DOES NOT IMPEDE ACCESS BY PATIENTS

The European Union presenting its new Trademark Directive during this week's meeting of the World Trade Organization intellectual property council heard concerns of possible seizures of generic medicines transiting through Europe. Meanwhile, the new Council chair's attempts at revitalising discussions between member states received general approval. And a new agenda item on e-commerce was launched. The WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS) took place from 5-6 June. The European Union presented the new EU Trademark Directive of December 2015. According to the EU statement, "the main objectives of the trademark reform were to foster innovation and economic growth by making trademark systems all over Europe more accessible, efficient and effective for businesses and to ensure and develop coexistence and complementarity between the EU and national trademark systems." *Read more*

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5. If India signs RCEP, it will not be the 'pharmacy of the world': MSF

DATA EXCLUSIVITY IS A FORM OF LEGAL MONOPOLY PROTECTION FOR A DRUG, OVER AND ABOVE THE PATENT PROTECTIONS

Humanitarian aid organisation Médecins Sans Frontières (MSF) has warned India that the country will not remain 'pharmacy of the developing world' if the proposals in the Regional Comprehensive Economic Partnership agreement (RCEP) are adopted. The RCEP is a regional trade agreement being negotiated between the 10 ASEAN countries currently in Auckland.

MSF Access Campaign along with other civil society organisations are pushing for the removal of harmful intellectual property provisions that could potentially increase drug costs by creating new monopolies and delaying the entry of affordable generics in the market. [Read more]

6. UN Development Agency issues guidelines for pharmaceutical Patent examiners

PROPER APPLICATION OF PATENTABILITY STANDARDS CAN PREVENT THE GRANT OF 'POOR QUALITY' OR TRIVIAL PATENTS

A new set of guidelines for pharmaceutical patent examination has been published by the United Nations Development Programme that seek to help reduce poor quality patents and ensure efficient market entry of generic products.

The guidelines, written by a well-known advocate of access to medicines, aim at advising patent examiners in assessing the patentability requirements of applications relating to pharmaceutical products and processes. The Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective "do not intend to modify the standards of patentability established by patent law, or to add additional standards," the document says. [Read more]

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7. US Supreme Court lowers bar to larger Patent damage awards

TWO-STAGE TEST WAS DESIGNED TO AVOID DISTORTING THE BALANCE BETWEEN PROTECTING PATENT HOLDERS AND TECHNOLOGY INNOVATION

The US Supreme Court issued a ruling Monday that makes it easier for patent holders to seek enhanced damages in infringement lawsuits, which could potentially triple the size of damages awarded.

Under the unanimous decision, federal district courts will have more freedom to decide when to award enhanced damages. These types of punitive damages allow plaintiffs to seek an award that is three times the amount of actual damages in a case.

Prior to the ruling, federal district courts faced "unduly rigid" tests in determining whether punitive enhanced damages could be awarded in patent infringement cases, according to the court's opinion posted on its website. Read more

8. Govt issues Patent guidelines for Indian startups; facilitator must for filing Patents

A LIST OF AROUND 280 FACILITATORS HAS BEEN PROVIDED BY THE PATENT OFFICE

Indian Patent Office or IPO has introduced new policy framework for Indian entrepreneurs. These new policy features would be the guidelines for those entrepreneurs who wish to file for patents, related with any industry.

As per the new policy, a facilitator is now a must for filing a new patent (to be discovered here); and in case the entrepreneur is not able to locate one, then he or she is encouraged to contact the Head of Patent Office of that respective city and 3 new facilitators would be provided by him.

Overall, this is a welcome step, aimed to boosting patents from Indian technologists and entrepreneurs, and promoting the culture of innovation among them. These guidelines would be followed for patents, designs and trademarks. Read more

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9. Intellectual Property Court established in Ukraine

THE COMPETENCE OF A JUDGE IS PARTICULARLY IMPORTANT IN PATENT DISPUTES

After a decade of disputes and lobbying, Ukraine has finally joined the countries with special IP courts or patent courts, namely the United Kingdom, the United States, China, Brazil, Germany, Sweden, Japan, Chile, France, Peru, Portugal, Russia, Spain and others.

On June 03, 2016, the Parliament of Ukraine adopted a law on reforming the judicial system of Ukraine. Currently, the law is awaiting the President's signature. The reform provides for establishing the High Court on Intellectual Property Issues by autumn 2017 as a court of the first instance for copyright, trademark and patent disputes. Judicial decisions will be reviewed in the court of appeal within the chamber of the Supreme Court of Ukraine."
Read more

10. Patent office caps fast-track requests

THERE IS A NEED TO HAVE MORE PATENT EXAMINERS WITH TECHNICAL SKILLS

The government, which opened a 'tatkal' window to expedite examination of patent applications in the backdrop of 2.37 lakh pending patent applications, has now set a limit on applications that it will consider under the fast-track clearance mechanism.
In a notice on June 14, the Controller General of Patents, Designs and Trade Marks said in terms of the provisions relating to expedited examination of applications, the number of requests for expedited examination to be received by the Patent Office on or before December 31, 2016 has been limited to 1,000 requests. The notice did not specify any reasons for imposing the cap on the number of applications. The 'tatkal' window was opened after the amendments to the patent rules came into effect from May 16.
Read more

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11. Biotech, devices cos should take advantage of Govt's 'ease of doing business' & IPR policy to step up making critical components: DBT secretary

THE ANCILLARY SECTOR IN BIOTECH AND MEDICAL DEVICES WILL NOW NEED TO FOCUS ON INNOVATION

Biotech and medical device start ups can now take maximum advantage of Union government's ease of doing business initiative and National Intellectual Rights (IPR) policy to pursue a promising technology development programme in the country, said Prof. K VijayRaghavan, secretary, department of biotechnology. In this regard, the early stage biotech and medical device companies need to take a cue from ancillary manufacturers in the electronics and automobile sectors in the country to make products that are critical components for a larger device or equipment. This would demonstrate the start up companies' sustainability advantage, he added. Read more

12. "We are seeing increasing use of our systems by Indian enterprises"

THE OVERWHELMING IMPRESSION ONE GETS WHILE INTERACTING WITH INDIAN BUSINESSES IS THAT OF OPTIMISM.

World Intellectual Property Organization (WIPO) is a Geneva-based, self-funding agency of the United Nations, striving to encourage creativity and innovation among its 188 member countries. In an exclusive interview with Business Today's Joe C. Mathew, WIPO Director General Francis Gurry talks about the emerging areas in intellectual property (IP) and the potential it holds for countries like India. Edited excerpts:

India is considered a bright spot in the global economy by almost every international agency today. Does WIPO share the same view?

I think so. Read more

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13. Government permits 74 % FDI under automatic route for brownfield pharmaceuticals

AMENDMENTS TO THE FDI POLICY ARE MEANT TO LIBERALISE AND SIMPLIFY THE FDI POLICY SO AS TO PROVIDE EASE OF DOING BUSINESS

At a meeting chaired by Prime Minister Narendra Modi, the government has made changes to the FDI policy in pharmaceutical sector with the objective of providing major impetus to employment and job creation in India. With the objective of promoting the development of this sector, it has been decided to permit up to 74 per cent FDI under automatic route in brownfield pharmaceuticals and government approval route beyond 74 per cent will continue. The extant FDI policy on pharmaceutical sector provides for 100 per cent FDI under automatic route in greenfield pharma and FDI up to 100 per cent under government approval in brownfield pharma. Read more

14. Heading for Brexit: Will United Kingdom's Intellectual Property protections Brexit too?

WHAT IS LESS CLEAR IS THE IMMEDIATE AND LONG-TERM FUTURE OF THE UNITARY PATENT AND THE UNIFIED PATENT COURT (UPC)

With the full effect of the June 23 United Kingdom (UK) vote – known as Brexit – to leave the European Union (EU) still unclear, those seeking protection of their intellectual property in the EU and the UK have a varied landscape to navigate. The UK's exit from the European Union will take at least two years and possibly much longer. During that period, EU IP will be protected in the UK just as it is today. The effect on patents is somewhat limited, whereas the impact on trademarks and designs is likely to be more significant.

Even after Brexit, the European Patent Office (EPO) will continue to examine and grant European Patents because the EPO is not an EU body. Read more

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