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The Andhra Journal of Industrial News

IP and Industry News

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Issue 128

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One and a Half Million Dollar Drug

The first gene therapy drug Glyberaⁱ, developed by UniQure, is set to go on sale in Germany with a 1.1 million euro (\$1.4 million) price tag, in the first half of 2015. Under German rules, the launch price for a new drug is valid for the first 12 months. The new drug fights an ultra-rare genetic disease called lipoprotein lipase deficiency (LPLD) that clogs the blood with fat. The medicine was approved in Europe two years ago but its launch was delayed to allow for the collection of six-year follow-up data on its benefits. After a quarter century of experiments and several setbacks, gene therapy has finally arrived, with only 150 to 200 patients likely to be eligible for Glybera across Europe. The drug consists of a harmless modified virus that carries a corrective gene into the patient's cells. UniQure, Bayer, Dimension Therapeutics, Novartis, Sanofi, and Oxford BioMedica.

Peer-Review Riggingⁱⁱ

In the past 2 years, journals have been forced to retract more than 110 papers in at least 6 instances of

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peer-review rigging. The cases involved publishing behemoths Elsevier, Springer, Taylor & Francis, SAGE, Wiley, and Informa. When reviewers are invited to read a paper, they are sent an e-mail with login information. If that communication goes to a fake e-mail account, the recipient can sign into the system under whatever name was initially submitted, with no additional identity verification. Security loopholes can do more than compromise peer review. Because people often use the same or similar passwords for many of their online activities — including banking and shopping — e-mailing out the password presents an opportunity for hackers to do more than damage the research record.

Guidance on Subject Matter Eligibilityⁱⁱⁱ

The United States Patent and Trademark Office (USPTO or Office) has prepared interim guidance (2014 Interim Guidance on Patent Subject Matter Eligibility, called “Interim Eligibility Guidance”) for use by USPTO personnel in determining subject matter eligibility under 35 U.S.C. 101 in view of recent decisions by the U. S. Supreme Court (Supreme Court). This Interim Eligibility Guidance supplements the June 25, 2014, Preliminary Examination Instructions in view of the Supreme Court decision in Alice Corp. (June 2014 Preliminary Instructions) and supersedes the March 4, 2014, Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (March 2014 Procedure) issued in view of the Supreme Court decisions in Myriad and Mayo. The USPTO is seeking public comment on this Interim Eligibility Guidance along with additional suggestions on claim examples for explanatory example sets.

Reduction of Trademark Fees at the USPTO^{iv}

Effective on January 17, 2015, the United States Patent and Trademark Office (USPTO) reduces certain trademark fees, reducing total trademark fee collections. It is expected reductions would further USPTO strategic objectives to increase the end to-end electronic processing of trademark applications by offering additional electronic application processing.

DuPont Factors in *Inter Partes* Proceeding^v

In an *inter partes* trademark proceeding, the burden to introduce evidence that the goods were related is on the plaintiff, according to TTAB. Recently, in *In Re Franciscan Vineyards, Inc.*, the TTAB determined that there was no likelihood of confusion, under the relevant DuPont factors, between Franciscan’s previously registered marks for use with wine and Domaine Pinnacle’s requested mark for use with apple juice and apple-based non-alcoholic beverages because Franciscan failed to present

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evidence that the goods at issue were related. The TTAB refused to find a prior case controlling, in which the Board took judicial notice of dictionary definitions of “wine” and “cider” and found the goods related. That case, however, was an *ex parte* proceeding where the TTAB would be more permissive with respect to admissibility and probative value of evidence. The present case was an *inter partes* proceeding in which the burden was on Franciscan to introduce evidence that the goods were related.

The United States Patent and Trademark Office (USPTO) examines^{vi} every trademark application for federal registration of a trademark for compliance with federal law and the Trademark Rules of Practice. One of the most common reasons for refusing registration is that a “likelihood of confusion^{viii}” exists between the mark in the application and a previously registered mark or a pending application with an earlier filing date owned by another party. Likelihood of confusion exists between trademarks when the marks are so similar and the goods and/or services for which they are used are so related that consumers would mistakenly believe they come from the same source. Each application is decided on its own facts, and no strict mechanical test exists for determining likelihood of confusion.

In *In re E. I. du Pont de Nemours & Co.*, 476 F.2d 1357, 177 USPQ 563 (C.C.P.A. 1973), the Court of Customs and Patent Appeals discussed the factors relevant to a determination of likelihood of confusion. In *ex parte* examination, the issue of likelihood of confusion typically revolves around the similarity or dissimilarity of the marks and the relatedness of the goods or services. The other factors listed in *du Pont* may be considered only if relevant evidence is contained in the record. The Board evaluated several of the *DuPont* factors established. The Board conducted the likelihood of confusion inquiry pursuant to the thirteen factors set forth in *du Pont*:

- (1) The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression.
- (2) The similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use.
- (3) The similarity or dissimilarity of established, likely-to-continue trade channels.
- (4) The conditions under which and buyers to whom sales are made, i.e. “impulse” vs. careful, sophisticated purchasing.
- (5) The fame of the prior mark (sales, advertising, length of use).

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- (6) The number and nature of similar marks in use on similar goods.
- (7) The nature and extent of any actual confusion.
- (8) The length of time during and conditions under which there has been concurrent use without evidence of actual confusion.
- (9) The variety of goods on which a mark is or is not used (house mark, “family” mark, product mark).
- (10) The market interface between applicant and the owner of a prior mark
- (11) The extent to which applicant has a right to exclude others from use of its mark on its goods.
- (12) The extent of potential confusion, i.e., whether *de minimis* or substantial.
- (13) Any other established fact probative of the effect of use.

China and USFDA

Of the 200 countries that export their products to the United States, China ranks the first (in dollar value) largest exporter, the sixth largest provider of food and the sixth largest provider of drugs and biologics. Only the United States has more FDA-registered drug establishments than China. And these numbers are growing. Between 2007 and 2013, China’s annual exports of FDA-regulated products to the U.S. nearly quadrupled, reaching 5.2 million “lines” (portions of a shipment) of imported goods in 2013. Ensuring the safety and quality of these and other U.S.-destined FDA-regulated goods is a major challenge. To meet it, FDA has transformed itself— from a domestic agency that focused primarily on products manufactured in the U.S. to a truly global agency grappling with the many challenges of globalization. Among the many efforts in this area, an important component is the FDA’s establishment of permanent outposts staffed by FDA experts in all major exporting regions. US signed an Implementing Arrangement with the China Food and Drug Administration (CFDA).

Better Process to Enforce IP Exclusion Orders^{viii}

The Department of Homeland Security’s U.S. Customs and Border Protection (CBP) uses two processes to enforce exclusion orders issued by the U.S. International Trade Commission (ITC): a four-phase process to detect and deny entry to or seize infringing products at U.S. ports and an administrative ruling process that determines in advance of importing whether products are covered by exclusion orders. In the first phase of the process to enforce exclusion orders at the ports, CBP drafts a trade alert that provides enforcement instructions to CBP national targeting groups and local officials at all ports of entry to identify shipments for examination; without an alert, officials said, it would be difficult for CBP components to enforce an exclusion order. From September 2010 through April 2014, CBP excluded 158

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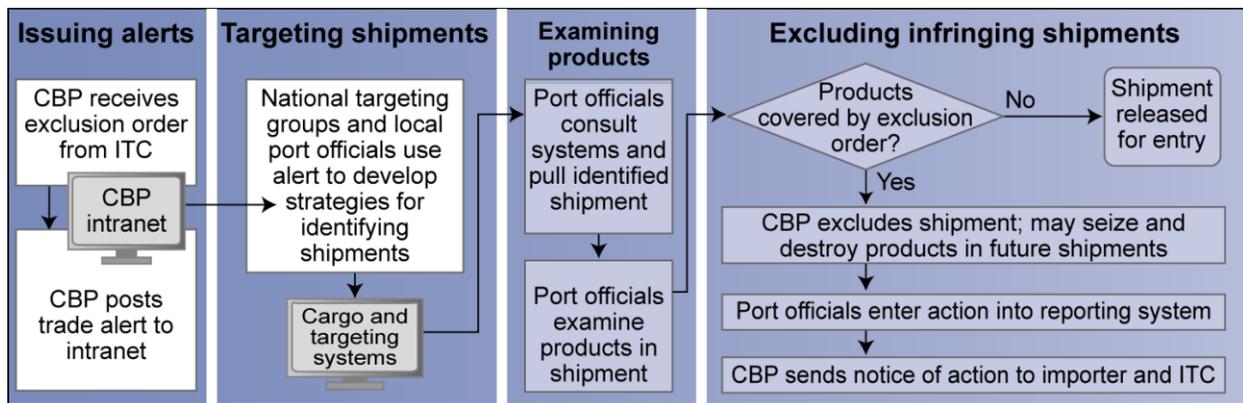
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shipments of products, such as ink cartridges and footwear. Before a company attempts to import a certain product, it may request that CBP determine through its administrative ruling process whether the product is covered by a particular exclusion order.



U.S.

Source: GAO analysis of CBP documents and interviews with CBP officials. | GAO-15-78
CBP U.S. Customs and Border Protection
ITC U.S. International Trade Commission

Customs and Border Protection's Process to Enforce Exclusion Orders at the Ports

CBP's management of its exclusion order enforcement process at the ports contains weaknesses that result in inefficiencies and an increased risk of infringing products entering U.S. commerce. First, CBP does not routinely review ITC's list of exclusion orders or take other action to ensure that a trade alert has been posted to its intranet for each order. At GAO's request, CBP reviewed ITC's list of exclusion orders as of April 30, 2014, and reported that it had posted trade alerts for 83 of the 94 exclusion orders; however, it posted 17 of the 83 trade alerts after GAO's request for data. Without routinely taking action to ensure that trade alerts are posted to CBP's intranet, infringing products could enter into U.S. commerce. Second, CBP does not routinely review ITC's list of exclusion orders to identify orders that may be candidates for rescission by ITC. Requesting rescission of exclusion orders could enable CBP to focus its enforcement efforts more effectively and efficiently. Third, CBP's guidance lacks time frames for issuing trade alerts, which prevents CBP from monitoring timeliness. GAO found that it took CBP from 2 days to 3 months to request a posting of a trade alert to the intranet during the period from October 2009 through April 2014. Without actively managing trade alerts and establishing time frames for posting alerts, CBP management

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cannot hold staff accountable for timely enforcement of exclusion orders, and there is an increased risk of infringing products entering U.S. commerce.

GAO recommends that CBP update its internal guidance with requirements to (1) routinely ensure that trade alerts are posted to the CBP intranet for each exclusion order, (2) routinely identify any orders whose changed conditions merit a CBP request that ITC rescind them, and (3) monitor timeliness of trade alert issuance. CBP concurred with recommendations one and three and described actions planned or under way to address them. However, CBP did not concur with recommendation number two. According to CBP, it is not mandated to identify potentially outdated orders and request that ITC rescind them. GAO continues to believe the recommendation is valid for reasons discussed in the report.

Digital Identity and Digital Divide

The next five years will see a flurry of technology innovation that will transform India as much as cell phones have over the past 15 years. This will be enabled by the availability of low-cost smart phones, the digital identity that India's Aadhar project has provided to hundreds of millions of people who lacked any documentation, and a host of exponential technology advances; A billion Indians will be joining the global economy during this decade, says Vivek Wadhwa^{ix}.

What Wadhwa meant by "a billion Indians joining the global economy" was that "a billion Indians joining to collect government benefits," because the new Indian government had indicated strong support for a controversial project to require residents to have biometric IDs in order "to collect government benefits," setting "a target of 1 billion enrollments by 2015^x." Biometric IDs are issued by the Unique Identification Authority of India (UIDAI), which assigns a person a 12-digit number called the Aadhaar number, requires the collection of 10 fingerprints, iris scans and other information such as the name, date of birth and address of the individual.

It has been criticized by a number of privacy groups who are concerned that the data could at some point be misused by the government for surveillance raising the concern about privacy, as the body is now being used as a password; while it is being presented as a very seductive vision of inclusion and belonging^{xi}.

The Supreme Court of India ruled in 2013 in an interim order that people not be required to have the

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Aadhaar identification to collect state subsidies, despite the Aadhaar number is proof of identity for a variety of services including banking and is voluntary. The Supreme Court has also ruled that illegal immigrants should not be enrolled under the Aadhaar program, which is meant to facilitate subsidized services to Indian citizens. The Aadhaar program does not collect citizenship information and is going to be misused by aliens, foreigners and illegal immigrants^{xii}. Critics say the project will turn India into an Orwellian police state that will spy on citizens' private lives^{xiii}.

Prime Minister Narendra Modi has said the nation “should feel shame” when women defecate in the open and plans to spend about \$30 billion to ensure most Indians have toilets by 2019. Bindeshwar Pathak’s Sulabh International has been making contribution in reducing India’s shame^{xiv}.

Notice: This material contains only general descriptions and is not a solicitation to sell any insurance product or security, nor is it intended as any financial, tax, medical or health care advice. For information about specific needs or situations, contact your financial, tax agent or physician.

Source: The primary sources cited above, New York Times (NYT), Washington Post (WP), Mercury News, Bayarea.com, Chicago Tribune, USA Today, Intellihealthnews, Deccan Chronicle (DC), the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, womenfitness.net, about.com, mondaq.com, etc.

Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!
(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)

ⁱGlybera: <http://www.reuters.com/article/2014/11/26/us-health-genetherapy-price-idUSKCN0JA1TP20141126>

ⁱⁱ Nature Volume: 515, Pages: 480–482 (27 November 2014); <http://www.nature.com/news/publishing-the-peer-review-scam-1.16400>

ⁱⁱⁱ2014 Interim Guidance on Patent Subject Matter Eligibility <https://s3.amazonaws.com/public-inspection.federalregister.gov/2014-29414.pdf>

^{iv}Reduction of Fees for Trademark Applications and Renewals <http://www.gpo.gov/fdsys/pkg/FR-2014-12-16/pdf/2014-29413.pdf> ;

Comments on Reduction of Fees http://www.uspto.gov/trademarks/notices/TEAS_RF_comments.jsp

^v *In Re Franciscan Vineyards, Inc.*, <http://www.cafcblog.com/wp-content/uploads/2014/12/In-Re-Franciscan-Vineyards-Inc.-No.-2014-1269-Dec.-9-2014.pdf>

An Empirical Study of the Multifactor Tests for Trademark Infringement:

<http://scholarship.law.berkeley.edu/cgi/viewcontent.cgi?article=1237&context=californialawreview>;

^{vi} Likelihood of Confusion http://tmsearch.uspto.gov/webaka/html/Likelihood/Likelihood_of_Confusion.html;

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^{vii} Likelihood of Confusion http://www.bitlaw.com/source/tmep/1207_01.html;

Likelihood of Confusion <http://www.americanuniversitylawreview.com/pdfs/42/42-3/gilson.pdf>;

^{viii} U.S. Customs and Border Protection Could Better Manage Its Process to Enforce Exclusion Orders: <http://www.gao.gov/products/GAO-15-78>

^{ix} Vivek Wadhwa is a fellow at Rock Center for Corporate Governance at Stanford University, director of research at Center for Entrepreneurship and Research Commercialization at Duke, and distinguished fellow at Singularity University. His past appointments include Harvard Law School, University of California Berkeley, and Emory University: <http://www.washingtonpost.com/blogs/innovations/wp/2014/12/31/why-2015-will-be-the-year-of-indias-next-technology-revolution/>

^x India's biometric ID project is back on track: <http://www.pcworld.com/article/2606152/indias-biometric-id-project-is-back-on-track.html>

^{xi} Does Size Matter? A Tale of Performing Welfare, Producing Bodies and Faking Identity: <http://www.thecrimson.com/article/2014/5/14/indian-biometric-identification-system/>

^{xii} Indian biometric ID project faces court hurdle: <http://www.pcworld.com/article/2049364/indian-biometric-id-project-faces-court-hurdle.html>

^{xiii} In Britain, a mandatory national ID system was scaled back to a voluntary pilot program beginning in Manchester. In the US, senators have proposed requiring all citizens and immigrants who want to work in the country to carry a new high-tech Social Security card linked to fingerprints as part of an immigration overhaul, while the voter ID issue has been the subject of contentious debate across the country, as a strategy to suppress the votes of minorities, the elderly, college students and the poor.
http://www.washingtonpost.com/wp-dyn/content/article/2010/03/27/AR2010032701460_2.html
http://www.washingtonpost.com/local/virginia-politics/virginia-voting-rights-groups-mobilize-for-election-day-and-new-photo-id-law/2014/10/29/156b071e-5fa1-11e4-9f3a-7e28799e0549_story.html

^{xiv} Modern Plumbing to Villages: <http://www.bloomberg.com/news/2014-12-30/mystery-surrounds-hanged-girls-as-india-village-embraces-toilets.html>

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