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VEPACHEDU EDUCATIONAL FOUNDATION

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IP and Industry News

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Dr. Rao Vepachedu[(1)], JD, PhD, LLM

Contents

FIRST CHEWABLE EXTENDED-RELEASE TABLET

Dose dumping is defined as unintended, rapid drug release in a short period of time of the entire amount or a significant fraction of the drug contained in a modified release dosage form. Depending on the therapeutic indication and the therapeutic index of a drug, dose-dumping can pose a significant risk to patients, either due to safety issues or diminished efficacy or both[2]. A modified release dosage form is intended to release the drug in desired concentrations for a prolonged period of time. A dosage form is said to be dose dumped when there is an excess release of drug at a particular time interval other than the stated or required amount. This results in higher systemic drug concentrations that may result in toxicity. The likelihood of dosedumping for certain modified release products when administered with food has been recognized for about twenty years and a regulatory process established to address it[3].

Chewing extended-release medications is typically dangerous because it can cause dose dumping, resulting in excessive concentrations of the drug in the body, or even toxicity. The first-ever FDA approval for a chewable extended-release tablet was granted recently to Tris Pharma[4].

VIDEO CONFERENCEWITH USPTO PATENT EXAMINERS[5]

Interviews provide an opportunity to discuss the application with the examiner and can be useful to clarify positions, resolve issues, and provide a better understanding of the application to both parties. The examiner's contact information can be found in the Conclusion section of the most recent Office action or from the Employee Locator on the USPTO web site. An applicant may also complete and submit an

Application Initiated Interview Request Form (PTOL-413A) to request an interview with an examiner. Some of the most productive interviews occur after a first action on the merits when both parties have had an opportunity to consider the prior art. Examiners are encouraged to have an interview whenever the interview can resolve issues and help further prosecution. A request for an interview prior to the first Office action is ordinarily granted in continuing applications. Normally, one interview after final rejection is permitted. Interviews may be held telephonically, via video conference, or in-person on a USPTO campus. Applicant may request any of these interview methods and such request will normally be granted. Since some examiners work remotely from a USPTO campus, there may not always be an opportunity for an in-person interview. However, these examiners are available for telephonic interviews and video conferences.

A video conference interview is a meeting with an examiner using a USPTO supplied web-based collaboration tool, such as WebEx[6], that permits participants to interact in real-time from anywhere using video and document sharing. When an applicant requests a video conference with an examiner, the request will normally be granted. All interviews held via video conference are to be originated or "hosted" by the USPTO. Thus the WebEx invitation must be sent by the examiner and not the applicant.

Written authorization from the applicant must be obtained prior to setting up a video conference. The following is a sample authorization which may be used by applicant and placed in the file-wrapper: "Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file[7]."

FEDERAL CIRCUIT ANNOUNCES PROPOSED CHANGE TO RULES[(8)]

The United States Court of Appeals for the Federal Circuit proposes to amend its Rules. This amendment is subject to public notice and comment under 28 U.S.C. § 2071(b). A summary of proposed amendments to the rules of practice and procedure is available at U.S. Court of Appeals for the Federal Circuit (CAFC) web site[(9)]. The proposed amendments are extensive and include incorporating the Administrative Order on Electronic Case Filing and conforming changes throughout, as well as other changes. The changes are presented in a track change format. Comments and suggested changes by members of the public should be

submitted by email to chiefdeputyclerk@cafc.uscourts.gov with a subject line of: PROPOSED RULES COMMENTS. Please clearly indicate at the beginning of each comment the number of the rule being commented upon. Please also include a return email address for the person submitting the comment, if different from the address from which the email comment is sent. For members of the public that do not have access to email, comments and suggested changes may also be submitted by mail to: Proposed Rules Comments, Clerk of Court, U.S. Court of Appeals for the Federal Circuit, 717 Madison Place, N.W., Washington, D.C. 20439. All comments must be received by close of business on Monday, January 4, 2016.

BIODIVERSITY[10]

"Biodiversity is not just a luxury for the rich, it is a necessity for the poor." - Pavan Sukhdev, Environmental Economist

Biodiversity is the variety of life, which includes Genetic Biodiversity and Ecological Biodiversity. Genetic Biodiversity is the variation in genes that exists within a species, e.g., all dogs are part of the same species, but their genes can dictate whether they are Chihuahua or a Great Dane. There can be a lot of variation in genes – just think about all the colors, sizes, and shapes that make up the genetic diversity of dogs. Ecological Biodiversity is the diversity of ecosystems, natural communities and habitats. There is more biodiversity within tropical ecosystems than temperate or boreal ecosystems. Tropical rainforests have the most diversity. The most diverse group of animals is invertebrates.

Biodiversity is extremely important to people and the health of ecosystems. Biodiversity allows us to live healthy and happy lives. It provides us with an array of foods and materials and it contributes to the economy. Most medical discoveries to cure diseases and lengthen life spans were made because of research into plant and animal biology and genetics. They include everything from cleaning water and absorbing chemicals, which wetlands do, to providing oxygen for us to breathe—one of the many things that plants do for people. Biodiversity allows for ecosystems to adjust to disturbances like extreme fires and floods. Genetic diversity prevents diseases and helps species adjust to changes in their environment.

Conserving the diversity of life on earth is fundamental to human well being. Once considered a niche issue or special interest, biodiversity conservation is now recognized as critical to achieving equitable and sustainable development(11).

Every country has important biodiversity, but biodiversity is concentrated in tropical forests, where 70 percent of all plants and animals live. However, out of more than 196 countries in the world, about 70% of the entire world's biodiversity is in only 17 countries, called megadiverse countries(12). Conservation International identified these megadiverse countries in 1998. The identified Megadiverse Countries are: United States of America, Mexico, Colombia, Ecuador, Peru, Venezuela, Brazil, Democratic Republic of Congo, South Africa, Madagascar, India, Malaysia, Indonesia, Philippines, Papua New Guinea, China, and Australia.

India boasts about 8% of the world's species with an estimated 45,000 plants and 91,000 animal species and 1/5th of world's human population (one species – Homo sapiens) with only 2.4% of the total land in the world(13), while Brazil is the most biologically diverse country in the world, with approximately about 70% of the world's catalogued animal and plant species. Brazil's rich biodiversity allows the country to produce a wide variety of plant, animal and microbe based food, drugs, cosmetics, fibers and building materials. More than 200,000 species are now known from the United States(14).

A host of countries signed the Biological Diversity Convention (BDC) in Rio in 1992. The goal of the convention was the sustainable use of biological diversity and sharing of benefits derived from the use of genetic resources.

India is party to the Convention on Biological Diversity (CBD) 1992 which recognizes the sovereign rights of states to use their own Biological Resources. In order to help in realizing the objectives of CBD, India has enacted an umbrella legislation called the biological Diversity Act 2002 (No.18 of 2003)(15) aimed at conservation of biological resources and associated knowledge as well as facilitating access to them in a sustainable manner and through a just process.

More than two decades later, in November 2015, a new law in Brazil(16) came into regarding access to genetic resources and associated traditional knowledge, requiring sharing of benefits deriving from

commercialization of a final product or reproductive material developed from such components. The pharmaceutical, food, cosmetics, biotechnology and agricultural sectors that exploit genetic or traditional knowledge are subject to the New Law. Some of the obligations include:

*****The benefits from commercial exploitation of a finished product or a reproductive material, even if produced abroad, that derives from access to genetic resources or traditional knowledge must be shared with indigenous people, local communities and the National Sharing Benefits Fund (article 17 of the New Law)

*The genetic resources or the associated traditional knowledge component in a final product must be one of its key elements and essential in its production and functional benefits or in its commercial exploitation (article 2 section XVIII and article 17 of the New Law)

*The obligation to share benefits of a final product derived from genetic resources or traditional knowledge is imposed exclusively on manufacturers of a finished product and primary producers of reproductive materials, regardless of whether others have previously utilized these products (article 17, paragraph 1 of the New Law)

*****Companies exploiting genetic resources and associated traditional knowledge from unknown sources are required to make a one-off payment to the National Sharing Benefits Fund of 1% (one per cent.) of the net sales revenue that results from the sale of a final product or materials derived from genetic resources. The amount payable to the National Sharing Benefits Fund may be reduced if companies in the same sector collectively sign an agreement with the government to reduce such payment, in which case the law authorizes a reduction of up to 0.1% (zero point one per cent.) of the companies' annual sales revenue (articles 20, 21, 23 and 25 of the New Law)

*****Companies exploiting associated traditional knowledge from known sources that retain such knowledge may engage in free negotiations as to the sharing of benefits deriving from the exploitation of such knowledge. In addition, 0.5% (zero point five per cent.) of companies' net sales revenue derived from such products must be paid to the National Sharing Benefits Fund for so long as the product is being commercialized (article 24, paragraph 3 and article 25, paragraph 1)

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REFERENCES AND NOTES

[1] Dr. Rao Vepachedu is the Managing Director at Cardinal Risk Management and registered patent attorney with extensive experience in the management of intellectual property and extensive experience in research and teaching. He currently works for Cardinal Intellectual Property (CIP), Cardinal Risk Management (CRM), and Cardinal Law Group (CLG). In addition, he is the president of Vepachedu Educational Foundation Inc. (www.vepachedu.org), a 501(c) (3) educational foundation. For more information visit: www.linkedin.com/in/vepachedu; http://www.avvo.com/attorneys/60201-il-sreenivasarao-vepachedu-764535.html, and http://www.crm-ip.com/vepachedu.html. Contact: svepachedu@yahoo.com or rao.vepachedu@cardinal-ip.com: www.linkedin.com/in/vepachedu and http://www.crm-ip.com/vepachedu.html;

http://www.avvo.com/profile/dashboard.

(2) Meyer et al., Awareness Topic: Mitigating the Risks of Ethanol Induced Dose Dumping from Oral Sustained/Controlled Release Dosage Forms U.S. Department of Health and Human Services, Food and Drug Administration, Center for Drug Evaluation and Research (CDER), U.S. Government Printing Office: Washington, DC, 2005; http://www.fda.gov/ohrms/dockets/ac/05/briefing/2005-4187B1_01_08-Alcohol-Induced.pdf
Jedinger et al., The design of controlled-release formulations resistant to alcohol-induced dose dumping – A review, Volume 87, Issue 2, Pages 217–226 (July 2014)
Friebe et al., Alcohol-induced dose dumping intentional / accidental –IPEC Working Group, 2015 IPEC Europe Excipients Forum Nice, France February 5th, 2015; http://ipec-europe.org/UPLOADS/10_T_Friebe.pdf
(3) Guidance for Industry: Food effect guidance Food-Effect Bioavailability and Fed Bioequivalence Studies (Issued 12/2002, Posted 1/30/2003); http://www.fda.gov/cder/guidance/5194fnl.pdf
(4) Tris Pharma Announces First Ever FDA-Approved Extended-Release Chewable Tablet; http://www.trispharma.com/news_erchew2015.php
(5) Video Conference Interviews with Patent Examiners https://www.youtube.com/watch?v=i1pDYTPzI50&feature=youtu.be
(6) WebEx Tips: http://www.uspto.gov/patents/resources/web_conferencing.jsp
(7) see MPEP502.03 for further guidance on written authorization
(8) United States Court of Appeals for the Federal Circuit Rules of Practice:
http://www.cafc.uscourts.gov/sites/default/files/rules-of-practice/ProposedRules/federal_circuit_rules_public_notice_dec_2015.pdf
(9) Summary of Proposed Amendments to the Rules of Practice and Procedure, U.S. Court of Appeals for the Federal Circuit:
http://www.cafc.uscourts.gov/sites/default/files/rules-of-practice/ProposedRules/summary_of_proposed_rule_changes_dec_2015.pdf
[10] What is Biodiversity? http://nwf.org/Wildlife/Wildlife-Conservation/Biodiversity.aspx
[11] CONSERVING BIODIVERSITY AND FORESTS: https://www.usaid.gov/biodiversity
[12] Megadiverse countries: https://www.youtube.com/watch?v=2mlX-SZqaXo
[12] Indian Biodiversity Information System (IBIS): http://www.indianbiodiversity.org/ ;
http://www.undp.org/content/india/en/home/presscenter/articles/2015/08/25/COI-biodiversity-awards-2016.html
Biodiversity of India: http://www.isid.ac.in/~som/papers/BiodiversityinIndia_rev.pdf
[13] Precious Heritage: The Status of Biodiversity in the United States: http://www.natureserve.org/biodiversity-science/publications/precious-heritage-status-biodiversity-united-states
[14] Biological Diversity Act 2002 and establishment of National Biodiversity Authority, Chennai:
http://www.moef.nic.in/sites/default/files/Ministry%20of%20Environment.pdf
The Biological Diversity Act 2002: http://nbaindia.org/; http://nbaindia.org/content/25/19/1/act.html; in Telugu:
http://nbaindia.org/uploaded/ActBook_Telugu.pdf
[15] Presidency of the Republic, Law No. 13,123: http://www.planalto.gov.br/CCIVIL_03/_Ato2015-2018/2015/Lei/L13123.htm
http://www.managingip.com/Article/3482780/India-Laws-on-biological-diversity-in-India-and-Brazil.html

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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!)

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