FDA / PTO Coordination Frequently Asked Questions

The Medication Affordability and Patent Integrity Act (H.R. 5429)

Would the FDA be violating trade secrets if they were to provide information to U.S. patent examiners regarding inventions being claimed in patent applications?

The legislation does not require the U.S. Food & Drug Administration (FDA) to provide any information to the U.S. Patent and Trademark Office (USPTO). Instead, the bill requires the patent applicant to provide information to the patent office that it previously disclosed to the FDA. The patent applicant can use its discretion to select and provide only the information that is "*material to the patentability of the patent application*". Thus, there is no risk that the FDA accidentally over-discloses or shares information that goes beyond the patentability of the patent application.

If the patent applicant fails to provide this information to the patent office, then any party that is subsequently accused of infringing the patent will be entitled to a defense that the patent is not enforceable against them. Therefore, the patent applicant should be careful to be inclusive of all relevant discloses, but nonetheless, maintains control over exactly which disclosures are provided to the patent office.

Will the patent office publish the information that is submitted by the patent applicant? Does this mean that "trade secrets will be disclosed"?

The information received from the patent applicant will become part of the patent application file wrapper, which is accessible online. However, the information is not a trade secret because it is material to the patentability of the patent application. It is not possible to patent a trade secret. The act of filing a patent application requires that the invention is fully disclosed to the public. The bill allows the patent applicant to use its discretion to select and provide only the information that is "*material to the patentability of the patent application*".

Nothing is more fundamental to the Patent Act than the quid pro quo of gaining market monopoly in exchange for disclosing inventions to the public. In this case, an originator cannot expect FDA to keep "trade secrets" from the patent office, or any other entity, when they have already or intend to file a patent to gain monopoly protection.

As Judge Learned Hand explained in 1946 during the case *Metalizing Engineering Co. v. Kenyan Bearing & Auto Parts Co.*, "[I]t is a condition upon the inventor's right to a patent that . . . he must content himself with either secrecy or legal monopoly." [1]

[1] Metallizing Engineering Co. v. Kenyan Bearing & Auto Parts Co., 153 F.2d 516, 520 (2d Cir. 1946), *cert. denied,* 328 U.S. 840 (1946)

In the current environment, however, a branded drug company can obtain patents while still protecting the information necessary for making and using the drug. Although they are obtaining patents on the necessary structural features of a drug, critical manufacturing techniques, clinical trial protocols, and quality-control procedures, this information is currently being protected as trade secrets by the FDA, a circumstance that can impede and discourage biosimilar market entrance.[2]

Is it OK that originators are holding back inventions from the patent office until the product is on the market because they are losing monopoly years by patenting inventions before commercial launch of the product?

No. The time lost on the first patent filing and the commercial launch of the product is built into the current patent system. A patent term extension (PTE) was created in the Hatch-Waxman Act of 1984 and is the current mechanism to compensate inventors for patent term loss due to regulatory delay during the drug approval process by the FDA**.** An originator must apply for PTE on its patents that can benefit from PTE within 60 days of FDA approval. The PTE applications then get referred to the FDA for a count of the applicable regulatory review period. The USPTO and FDA can grant interim PTE until such time as they determine the PTE award that the originator would receive. At that time, the patentee will then select one patent to receive PTE, provided that the PTE does not exceed the lesser of five years additional patent life or 14 years post FDA approval.

Did they discover the element on which they are filing a patent later than the original invention, that was disclosed to the FDA in regulatory filings?

No. All the technical features of a drug's structure are required to be disclosed to the FDA at the time the drug enters clinical studies, which is years before the drug receives FDA approval. This is held as a trade secret by the FDA and is not available to patent examiners during patent examination.

What is the non-disclosure defense and how would it be used to prevent inconsistent statements by branded manufactures between FDA and UPSTO?

The non-disclosure defense is something that a biosimilar or generic challenger can use in district court litigation if the patent holder fails to disclose the required information to the both the FDA and the USPTO, or if it is found to have made inconsistent statements between the two agencies. The legislation does not charge either agency with enforcing this new disclosure rule, but instead allows a generic patent challenger to present and use the non-disclosure as evidence against an originator manufacturer before a judge during litigation, who may deem the patent unenforceable against the patent challenger. All information would be held as trade secrets by the FDA and this information would only be released to the patent challenger in a court preceding through the discovery process.

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[2] Feldman, R. (2023). Trade Secrets in Biologic Medicine: The Boundary with Patents. *Science and Technology Law Review*, *24*(1), 1–54. https://doi.org/10.52214/stlr.v24i1.10455