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BRIEFS

USPTO and Regulatory Agencies Tie the Knot

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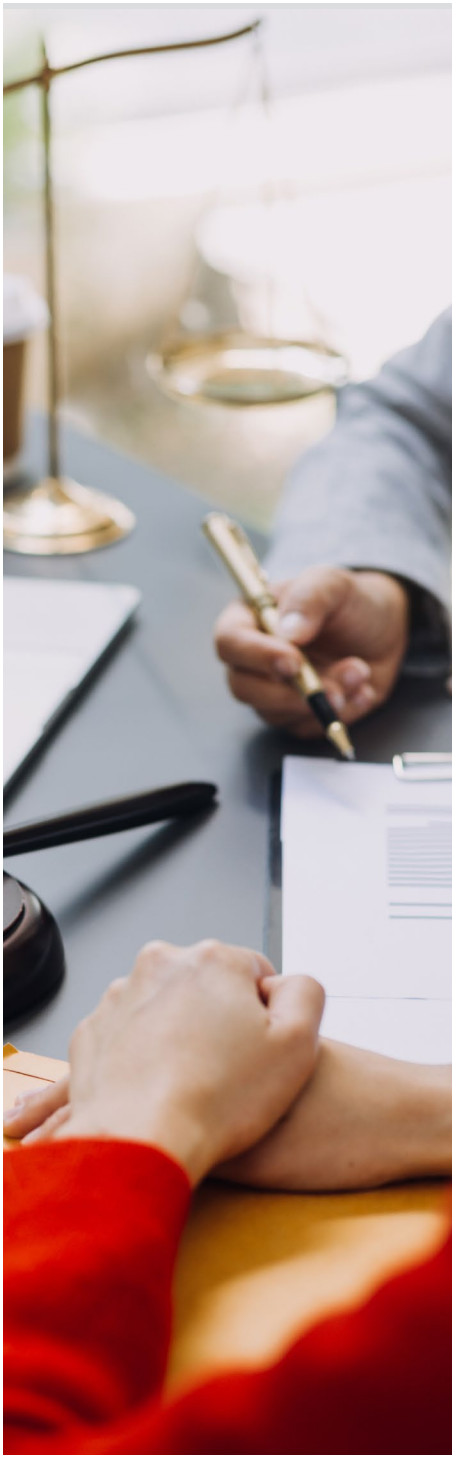

After many years of casual data sharing between agencies, the USPTO has formally announced its intentions to marry the duty of disclosure for patent prosecution with the regulatory process. This recent notice clarifies the scope of duties of inquiry and disclosure to the patent office, including statements made to the FDA and other regulatory agencies that are inconsistent with statements submitted to the USPTO.

Traditionally inventors focus on points of novelty in patent applications, with data supporting the message that the invention is different from anything seen before. However, when the product is regulated, converse arguments are often made with government agencies.

The invention in commercial form may be positioned to be substantially equivalent to what is already in the market. For the regulatory agencies, the story to be told from a risk perspective is that there is nothing new to see here – with supporting data as proof, comparing the new product side by side to existing products.

With this notice, the patent office emphasizes that each individual with a duty of inquiry and duty to disclose should ensure that the statements made to the USPTO and regulatory agencies regarding claimed subject matter, are consistent. See Belcher Pharms., LLC v. Hospira, Inc., 11 F.4th 1345 (Fed. Cir. 2021) (affirming a district court's determination of inequitable conduct because the patent owner's Chief Science Officer failed to provide to the USPTO submissions he made to the FDA about the prior art that were inconsistent with positions taken before the USPTO during the prosecution of a pending patent application).

Specifically, providing material information to regulatory agencies such as the FDA, while simultaneously withholding the same information from the USPTO, undermines and is a clear violation of the duty of disclosure. See Bruno Independent Living Aids, Inc. v. Acorn Mobility Services, Ltd., 394 F.3d 1348, 1354 (Fed. Cir. 2005) (the U.S. Court of Appeals for the Federal Circuit inferred intent to deceive, and found inequitable conduct occurred when a party involved in both the FDA and the USPTO submissions chose to disclose material prior art to the FDA but not to the USPTO).

The USPTO notice calls out that each individual with a duty of inquiry and duty to disclose should review documents it submits and receives from other government agencies, to determine whether the information should be submitted to the USPTO. Further, it states that simply choosing to separate patent from regulatory accountability does not relieve the applicant of this duty of disclosure: "walling off the patent prosecution practitioners from the attorneys seeking FDA approval, as a way to prevent material information from being exchanged between the practitioners and attorneys, is inappropriate." (Notice, p. 45767 col. 1).

In addition, this duty is retroactive and an applicant must disclose to the USPTO any information that refutes, or is inconsistent with, a position the applicant takes in asserting an argument of patentability, or opposing an argument of unpatentability. If a party to a USPTO proceeding discovers that an earlier position taken in a submission to the USPTO or another regulatory agency was incorrect or inconsistent with other statements made by the party, the party must promptly correct the record. See, e.g., In re Tendler, Proceeding No. D2013-17 (USPTO Jan. 1, 2014) (suspending a practitioner for four years for failure to correct the written record after learning of inaccuracies in a declaration the practitioner had filed).

As a result, the coordination of regulatory and patent strategies throughout the product lifecycle becomes more critical than ever. The consequences of making inconsistent statements between the patent office and regulatory agencies, or failing to disclose to the USPTO information material to patentability that is submitted to/sent from regulatory agencies, are severe. Failing to abide by this new union between the patent office and regulatory agencies may result in patent application rejection, patent invalidity, a finding of fraud and/or inequitable conduct, and disciplinary action against the patent practitioner.

Is Your Patent License Still Valuable and Valid?

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Is your patent license agreement still valuable and enforceable? If something has happened to the underlying patent or one of the underlying patents, it may not be.

It is hard and fast patent law that a patent license agreement cannot compel payment of royalties beyond the expiration of the underlying patent – known as Brulotte's Rule. (Brulotte v. Thys Co. where Justice Douglas stated for an eight-justice majority: "A patentee's use of a royalty agreement that projects beyond the expiration date of the patent is unlawful per se."). The underlying theory of Brulotte's Rule is that upon expiration, the technology disclosed and covered by the patent underlying the license agreement enters the public domain and, thus, becomes public property free for anyone to use without cost or other encumbrance.

In 2015, the United States Supreme Court decided the case of Kimble, et al. v. Marvel Entertainment, LLC. It dealt with a patent license agreement related to the web projecting gloves (utilizing foam string) of Spiderman sold as toys. Therein, SCOTUS reaffirmed the vitality of Brulotte's Rule. SCOTUS also commented on licenses which included more than grants under a patent. If, for example, the license agreement contained a valid recognition of trade secrets that were provided by the licensor to the licensee in conjunction with the patent grant, it is possible that the collection of royalties under the license may not violate Brulotte's Rule.

Two critical aspects and a question emerge from the overarching patent law. First, if rights to something more than a patent grant are involved in a patent license agreement, these additional grants of authority to the licensee should be called out with appropriate specificity. For a license to also include the grant of "know-how", it would appear that if the know-how relates to the technology of the patent, it should be subsumed by the patent and, therefore, would not provide an independent basis upon which to continue to charge royalties.

Second, if the nonpatent grant is legitimate, which excludes an illusory grant such as to patent rights which bear no relation to the product or process actually licensed and used by the licensee or undefined and unprovided trade secrets, then an independent valuation of the royalty amount needs to be included within the license. In other words, if the license provided for a royalty right of 5% of gross sales when patent rights were involved, should it be 1% or 2% when the patent no longer exists?

The question that remains under patent law is the impact of multi-patent license agreements, and an underlying failure by the licensor to possess a valid patent or otherwise hold or maintain a patent underlying the grant to the licensee. Under Brulotte's Rule, it is arguably a violation to allow the patent license agreement to survive when one or more of the underlying patents have expired and there is no economic adjustment built into the license. Yet, it is common for patent license agreements to attempt to tie duration of the royalty to expiration of the last of the patents in such an agreement – an interesting approach in light of the case of Rocform Corp. v. Acitelli-Standard Concrete Wall, Inc., wherein the Sixth Circuit Court of Appeals held it was patent misuse for a license to demand full royalty payments after the expiration of the most important patent in the group of patents licensed therein.

Harvested Material and Unauthorized Use of Propagating Material

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The International Union for the Protection of New Varieties of Plants (UPOV) is the intergovernmental organization established by the International Convention for the Protection of New Varieties of Plants, adopted in Paris in 1961. The Convention was subsequently revised in 1972, 1978 and, most recently, in 1991. The mission of UPOV is to "provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society".

Last year, the Working Group on Harvested Material and Unauthorized use of Propagating Material (WG-HRV) was established to address a perceived lack of effective and predictable protection for harvested material. Revisions of three Explanatory Notes are currently under consideration by the WG-HRV, namely the Explanatory Notes on Propagating Material, Acts in Respect of Harvested Material, and Provisional Protection. While the only binding obligations on members of the Union are those contained in the text of the UPOV Convention itself, the UPOV Council will occasionally adopt these Explanatory Notes for the purposes of providing further clarity to the provisions of the UPOV Convention.

Article 14(1) of the 1991 Act of the UPOV Convention provides that the following acts in respect of the propagating material of the protected variety require the authorization of the breeder: (i) production or reproduction, (ii) conditioning for the purpose of propagation, (iii) offering for sale, (iv) selling or other marketing, (v) exporting, (vi) importing, and (vii) stocking for any of the purposes mentioned in (i) to (vi). While this protection of propagating material is absolute, protection of harvested material comes with certain conditions. Specifically, Article 14(2) of the 1991 Act of the UPOV Convention requires that, in order for the breeder's right to extend to acts in respect of harvested materials, the harvested material must have been obtained through the unauthorized use of propagating material, and the breeder must not have had reasonable opportunity to exercise his right in relation to that propagation material. These conditions associated with harvested material and the guidance set forth in the current version of the Explanatory Notes have raised a number of questions and concerns, which the WG-HRV seeks to address.

First, there is the fundamental question of whether a particular plant material is "propagating material" or "harvested material". Most parties

agree that the Explanatory Notes would benefit from further clarification of these terms.

One proposal under consideration is to revise the Explanatory Notes to include the following:

> *When harvested material has the potential to be used as propagating material, it can be considered as propagating material.*

When the Convention was drafted in 1991, there was a much clearer distinction between harvested and propagating material. However, propagation technology has improved dramatically since that time such that there is now potential for virtually any plant material to be considered propagating material.

Article 14(2) requires that the harvested material was obtained through the unauthorized use of propagating material, but when is use considered unauthorized? One possible interpretation is that use is unauthorized if the breeder has not given authorization or consent to the use. A narrower interpretation is that the use is only unauthorized if such authorization was required but was not obtained. The Explanatory Notes on Harvested Material in their current form take the narrower interpretation. Specifically, paragraph 4 states:

> *"Unauthorized use" refers to the acts in respect of the propagating material that require the authorization of the holder of the breeder's right in the territory concerned (Article 14(1) of the 1991 Act), but where such authorization was not obtained. Thus, unauthorized acts can only occur in the territory of the member of the Union where a breeder's right has been granted and is in force.*

This narrow interpretation is particularly concerning when harvested material is used in a different country than the propagating material. For example, what if an offender reproduces a variety in a country where protection was not possible or was not obtained, harvests material from the variety, and then imports the harvested material back into a country where the variety is protected? In this scenario, is the owner of the protected variety able to prevent commercial sales of the harvested material?

Some of the proposed revisions are intended to address exactly this scenario. For example, a proposal from the Netherlands suggests revising the Explanatory Notes to include the following:

> *If harvested material is imported in a territory, whereby the use of the propagating material and consequently the production of harvested material have both taken place outside the territory of import, and there has been no act of authorization by the right holder in the territory of import, the use of the propagation material can be considered to be unauthorized.*

Another possibility is to instead use the broad interpretation of unauthorized use. This is the case with a proposal from AFSTA (African Seed Trade Association), APSA (Asia and Pacific Seed Alliance), CIOPORA, Crop Life International, Euroseeds, ISF (International Seed Federation), and SAA (Seed Association of the Americas), which suggests revising paragraph 4 to recite:

> *Authorization is the clear manifestation of an act of will from the side of the breeder. Therefore, "Unauthorized use" refers to the acts in respect of the propagating material, where no such explicit authorization from the breeder was obtained. The "Unauthorized use" condition should be construed to mean that the propagating material has been used without formal prior consent of the breeder.*

Precisely how the Explanatory Notes will be revised remains to be seen. The next meeting of the WG-HRV is now scheduled for March 21, 2023. Any changes from the WG-HRV would then need to be considered and agreed upon by the UPOV Administrative and Legal Committee (CAJ).

2022 Developments in Biometric Data Litigation: Arbitration Clauses of User Agreements Are Enforceable, Even For Minors

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The last two years have seen a significant acceleration in planned and executed biometric data collection. Consider, for example, the TSA's implementation of facial recognition technology[1] to verify identification and the primary schools in the U.K. implementing facial scanning for lunch payment.[2] Despite the controversy and concern raised by its use[3], biometric data collection is anticipated to increase substantially. Proponents argue biometric authentication serve important social interests, such as public safety.

However, biometrics technology appears to be outpacing legislative regulation, particularly in the U.S. The United States does not have a comprehensive federal biometrics law that applies to the collection, use, and storage of biometric data. Instead, there are a patchwork of laws and regulations at the federal and state levels that address biometric data and its privacy implications.

At the federal level, the main law that applies to biometric data is the Privacy Act of 1974[4], which establishes privacy protections for personal information that is collected, used, and shared by federal agencies. The Act applies to biometric data, but only in limited circumstances.

At the state level, there are a number of laws that address biometric data. The Illinois Biometric Information Privacy Act (BIPA)[5] is a state law that regulates the collection, use, and storage of biometric data by

private companies. The law applies to companies that collect biometric data, such as fingerprints or facial scans, for the purpose of identifying or tracking individuals. Under BIPA, companies are required to obtain written consent from individuals before collecting their biometric data and must also inform them of the specific purpose and length of time for which the data will be collected and stored. The law also includes provisions for the destruction of biometric data and imposes penalties for companies that violate the law.

BIPA has been widely recognized as one of the most comprehensive state laws governing biometric data and has served as a model for other states considering similar legislation. As such, it provides some of the only available guidance on biometrics litigation in the U.S. K.F.C. v. Snap Inc. was one of the most significant biometrics cases evaluated by the U.S. Courts of Appeal—specifically the 7th Circuit—at least because of its evaluation of how minors are impacted by personal data collection.[6] The plaintiff, a minor named only as "K.F.C.," alleged that Snap Inc., the company behind the popular social media app Snapchat, had violated the Computer Fraud and Abuse Act (CFAA) and other Illinois state laws through Snap's use of geofilters (customizable overlays that users can add to their photos to show their location). K.F.C. claimed that Snap Inc. had accessed her phone without their permission and used the geofilters to track their location without their knowledge or consent.[7] Relatedly, K.F.C. argued that some of Snapchat's features amounted to facial recognition and the collection thereof, and that this data was collected without consent and in violation of BIPA.[8]

The central issue, however, was whether K.F.C. was required to arbitrate her dispute with Snap Inc. In order to open a Snapchat account, users must agree to Snap's terms and conditions, one of which is the agreement to arbitrate disputes.[9] Users must also agree that they are older than 13 years of age, but K.F.C. lied about her age and created a Snapchat account when she was 11.[10] K.F.C. argued that because she was (and remained at the time of suit) a minor, K.F.C. lacked the ability to form a binding contract.[11] The 7th Circuit held K.F.C. to the arbitration clause of the user agreement, determining that "youth is a defense rather than an impediment to contractual formation" meaning the question of her age as a defense to enforcement must be considered in arbitration.[12]

The legal landscape for biometric data in the United States is complex and evolving. While there are some federal and state laws that address biometric data, there are still many gaps in the legal framework and uncertainty as to how existing laws should be applied—including application to minors. As biometric technology continues to advance and becomes increasingly ubiquitous, companies must be careful to comply with this expanding landscape while users must closely monitor the collection of their biometric data.

[1] Geoffrey A. Fowler, *TSA Now Wants to Scan your Face at Security. Here are Your Rights.* THE WASHINGTON POST (December 2, 2022) available at https://www.washingtonpost.com/technology/2022/12/02/tsa-security-face-recognition/.

[2] Sally Weale, *ICO to Step in After Schools Use Facial Recognition to Speed up Lunch Queue*, THE GUARDIAN (October 18, 2021) available at https://www.theguardian.com/education/2021/oct/18/privacy-fears-as-schools-use-facial-recognition-to-speed-up-lunch-queue-ayrshire-technology-payments-uk.

[3] See, e.g., Rob Davies, *'Conditioning an Entire Society': The Rise of Biometric Data Technology,* THE GUARDIAN (October 26, 2021) available at https://www.theguardian.com/technology/2021/oct/26/conditioning-an-entire-society-the-rise-of-biometric-data-technology.

[4] THE PRIVACY ACT, HHS.GOV available at https://www.hhs.gov/foia/privacy/index.html#:~:text=The%20Privacy%20Act%20of%201974,other%20identifying%20number%20or%20symbol.

[5] BIOMETRIC INFORMATION PRIVACY ACT, ILLINOIS GENERAL ASSEMBLY available at https://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=3004&ChapterID=57.

[6] *K.F.C. v. Snap Inc.*, 29 F.4th 835 (7th Cir. 2022).

[7] Id. at 836-67.

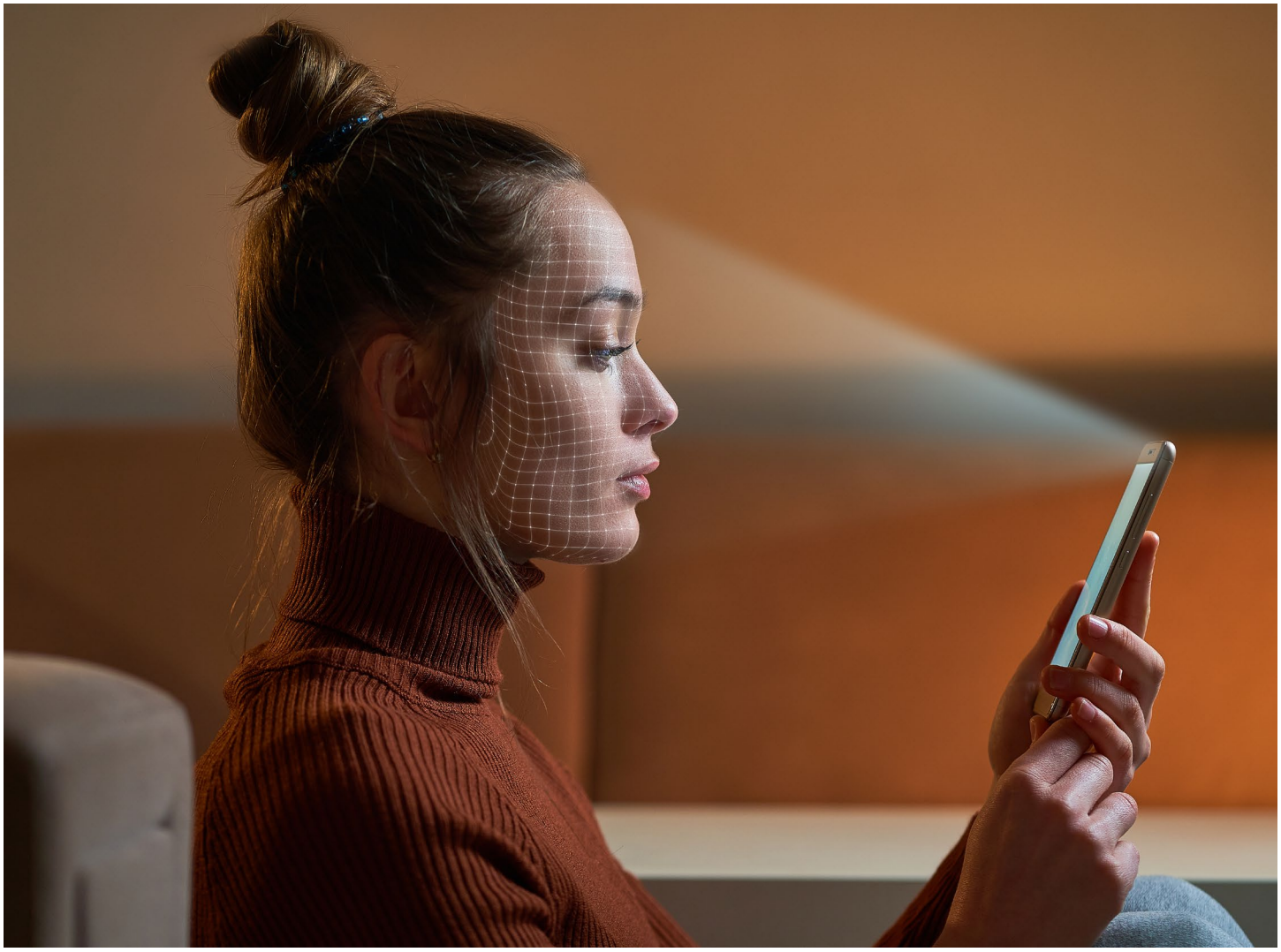
[8] Id.

[9] Id. at 837.

[10] Id.

[11] Id. ("K.F.C.'s argument starts with the proposition that, because arbitration is a matter of contract, judges must decide that a contract has been formed before they may order arbitration . . . K.F.C. adds . . . that a child cannot form a contract. This produces the conclusion that Snap does not hold any right to arbitrate with her, which means that the suit must proceed in court.")

[12] Id. at 838.



Protecting Your Roadmap: Lessons from Amgen v. Sanofi

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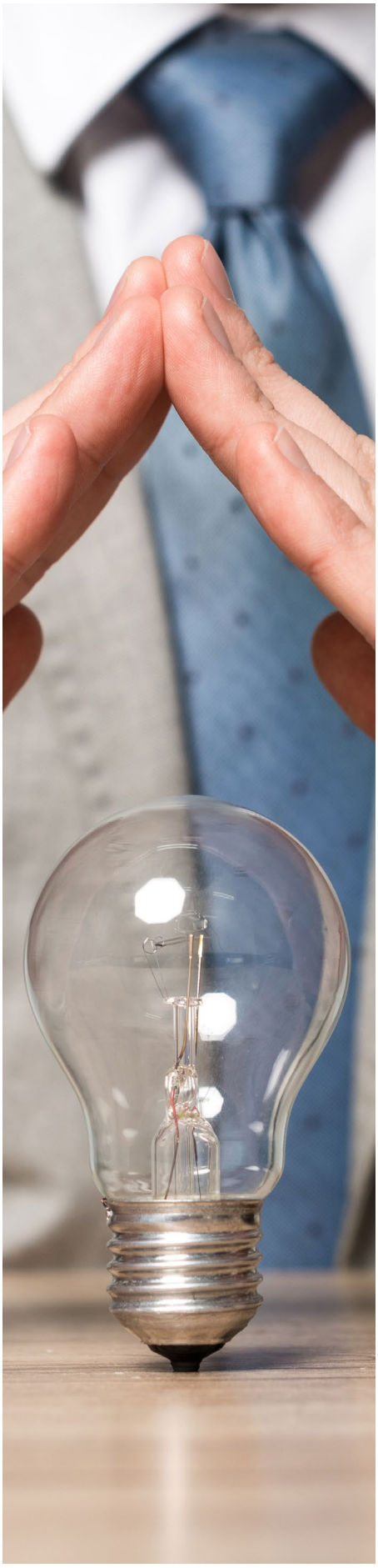
In exchange for teaching the public how to make and use their invention, patent holders are granted a time limited right to exclude others from using their invention as claimed. Should a competitor take those teachings and make an alternative that falls outside the patent holder's claims, the patent holder can not prevent their competitor from using the alternative and eroding their market share.

In Amgen v. Sanofi, Amgen faces the unenviable predicament of having set forth a detailed "roadmap" for obtaining valuable cholesterol-lowering antibodies only to have a competitor launch an alternative antibody which lowers cholesterol in essentially the same way. After failing to convince the Federal Circuit Court of Appeals that certain claims in their patents met the enablement requirement of 35 USC §112 (i.e., to make and use the invention as claimed), Amgen has successfully petitioned the US Supreme Court to hear their case in the upcoming term. At issue is whether patent holders "must teach those skilled in the art to "make and use" the claimed invention, 35 U.S.C. § 112, or whether it must instead enable those skilled in the art "to reach the full scope of claimed embodiments" without undue experimentation."[1] This "full scope" requirement is a much more stringent enablement standard which would require patent applicants "to cumulatively identify and make all or nearly all embodiments of the invention."[2] In the wake of this and other decisions on the "written description" requirement, the "Death of the Genus Claim" has been declared[3] and another amicus brief urging the Supreme Court to take on this case argued that the "full scope" enablement requirement of Amgen v. Sanofi creates "an impossible burden"[4] on patent applicants. In contrast, the Solicitor General unsuccessfully argued on behalf of the United States that a patent must enable an entire genus when it claims an entire genus based on its function[5] and that the Supreme Court should not review Amgen v. Sanofi.

Prudent patent applicants seeking claims with meaningful breadth will clearly need to adapt their claim strategies if the Supreme Court upholds Amgen v. Sanofi. The claims of the Amgen patents[6] in dispute are exclusively drawn to compositions of matter (i.e., isolated monoclonal antibodies and pharmaceutical compositions containing those antibodies) defined by functional characteristics. Amgen's composition claims did not meet the full scope of enablement requirement even in spite of extensive disclosures of 26 different monoclonal antibodies and a crystal structure of a representative antibody complexed with its therapeutic target which pinpoints the antibody binding sites set forth in



the claims. Although these Amgen patents describe in some detail methods for obtaining antibodies that fall within their claims, the '165 and '741 patents do not claim such methods. The methods for making the antibodies disclosed in the '165 and '741 patents constitute the "patents' step-by-step "roadmap," which teaches artisans to generate antibodies across the scope of the claims using "routine and well-known" techniques" described in the Amgen petition.[7] Patent applicants who disclose similar methods should clearly seek method claims that cover key method steps to keep competitors from merely following their "roadmap" to obtain compositions that fall outside the narrow composition claims deemed valid under the full scope enablement requirement.

Patent applicants may also consider limiting their "road map" method and "mode-of-action" disclosures in their patent applications if the Supreme Court upholds Amgen v. Sanofi. For example, patent applicants operating in fields where they are not required to immediately reveal such methods or modes of action to the public may want to disclose and claim more narrowly a particular product or subset of products that they intend to commercialize. While resultant claim coverage will be more limited, the patent applicant may at least avoid giving their competitors a head start on a "knock-off" product that falls outside narrow claims that would withstand a full-scope enablement requirement . While such limited disclosure would in fact "result in less, not more, disclosure of new ideas to the public" as Dr. Lemley and others have predicted[8], it may represent the best path to at least partial protection of a patent applicant's R&D investment.

[1] Petition for a Writ of Certiorari. S. Ct. 2021-757 (2021) (italics in original)

[2] Id. at page 2

[3] "The Death of the Genus Claim" Karstedt, D., Lemley, M.S., and Seymore, S.B. Harvard Journal of Law & Technology Volume 35, Number 1 Fall 2021

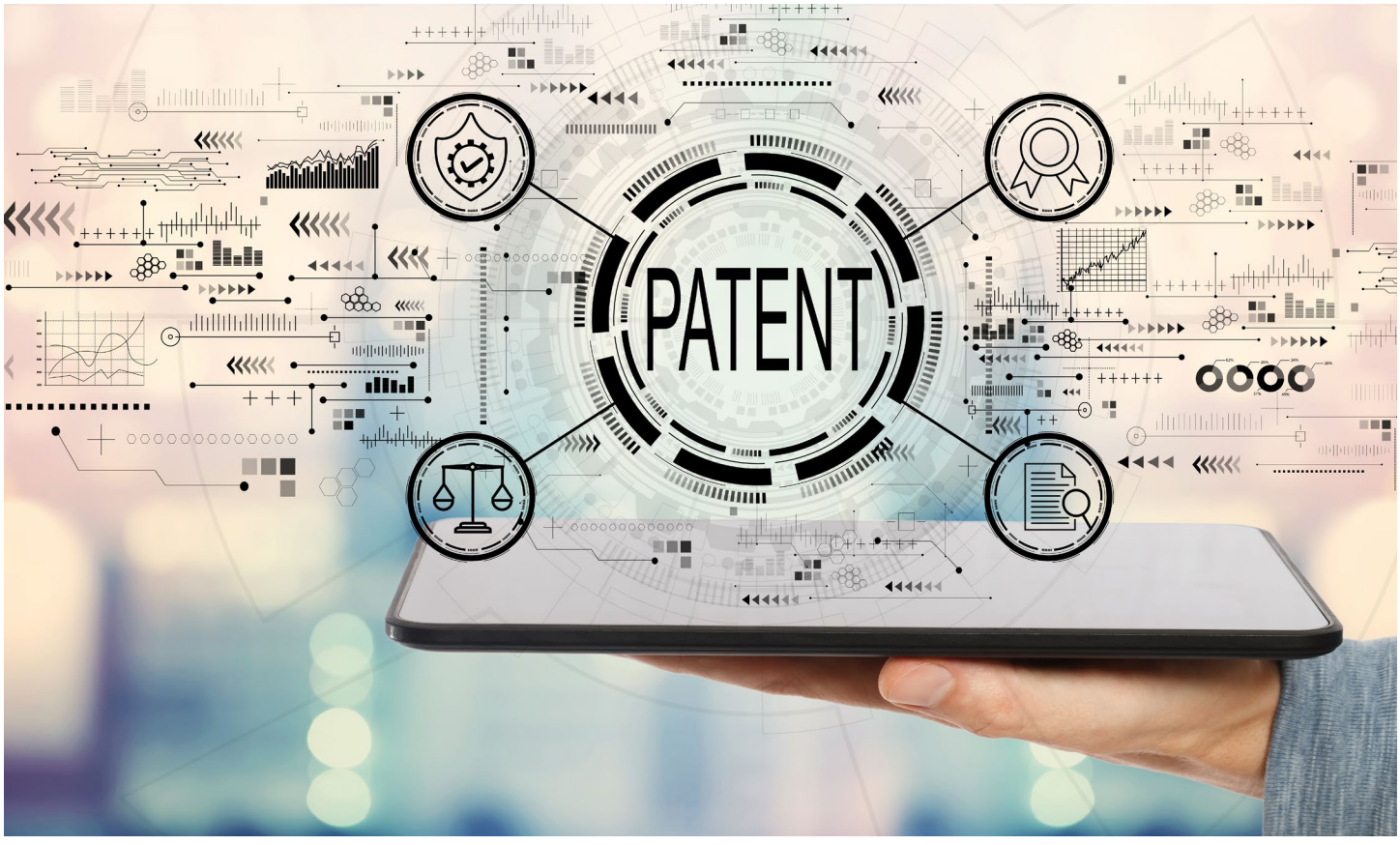
[4] Brief Of Intellectual Property Professors as Amici Curiae in Support of Petitioners S. Ct. 2021-757 (2021) at page 2, citing Karstedt et al.,supra.

[5] Brief amicus curiae of United States S. Ct. 2021-757 (2022)

[6] US 8,829,165 and US 8,859,741

[7] Petition for a Writ of Certiorari. S. Ct. 2021-757 (2021) at page 8

[8] Brief Of Intellectual Property Professors as Amici Curiae in Support of Petitioners S. Ct. 2021-757 (2021) at page 11



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