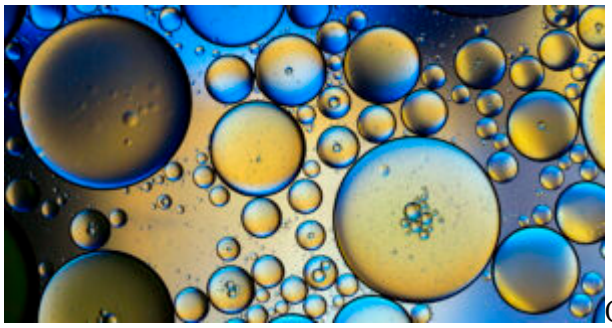
K-Fee Provides a Warning to Life Sciences Companies – What You Say in Foreign Prosecution May Affect Your U.S. Claim Scope

 On December 26, 2023, the United States Court of Appeals for the Federal Circuit issued its **decision** in K-Fee System GMBH v. Nespresso USA, Inc. While nominally a case related to coffee makers, its teachings are highly applicable to life science companies as they tend to file large numbers of ex-U.S. patent cases. The lesson: under certain circumstances, a court may consider statements made in patent prosecution proceedings outside of the U.S. when construing the scope of related U.S. claims, and as such those statements should be carefully weighed against implications in your U.S. patent portfolio.

K-fee System GmbH ("K-fee") owns U.S. Patent Nos. 10,858,176, 10,858,177, and 10,870,531. K-fee filed suit against Nespresso USA ("Nespresso") in the Central District of California ("District Court") alleging that Nespresso's coffee system infringed claims in each of the three patents. Nespresso filed a motion for summary judgment of non-infringement, arguing that its products did not infringe the asserted patent claims. The District Court agreed and granted Nespresso's motion for summary judgment. K-fee appealed to the Federal Circuit, which agreed with K-fee that the District Court erred in construing certain terms in the K-fee claims. The Federal Circuit remanded the case back to the District Court for further proceedings.

Previously, Nespresso had filed an opposition against a European patent related to the three U.S. patents K-fee asserted in its U.S. case. K-fee filed a motion asking the EPO to deny the opposition. K-fee argued that its claims were patentable over certain prior art cited by Nespresso based on the plain meaning of the term "barcode." In its motion, K-fee provided what it alleged to be the plain meaning of that term. K-fee provided the opposition filings to the USPTO, including the motion containing this claim construction argument. The District Court and the Federal Circuit would both treat K-fee's motion as intrinsic evidence as it had been made part of the U.S. file history by K-fee.

In deciding the motion for summary judgment in favor of Nespresso, the District Court referred to K-fee's definition of barcode provided in the opposition filings. Accordingly, the District Court accepted Nespresso's argument that its products fell outside of the asserted claims as interpreted according to the K-fee's proffered definition. K-fee appealed to the Federal Circuit, arguing that the District Court's narrowing of the term "barcode" was effectively a holding of disclaimer based on its prior arguments to the EPO, which, K-fee argued, did not meet the standard for disclaimer. In finding in favor of K-fee, the Federal Circuit held that the District Court's conclusion regarding the definition of barcode based on K-fee's EPO statements "was too confining," agreeing with K-fee that its arguments to the EPO did not rise to the level of disclaimer. The case was again remanded to the District Court for further proceedings.

The Federal Circuit concluded its opinion by writing “we note that K-fee makes the legal argument that a conclusion of disclaimer cannot be premised on statements made when defending a related but distinct patent against a different legal standard—here the European standard for novelty. We do not address that contention because we have concluded that K-fee’s statements were too unclear to constitute disclaimer.”

PTAB Issues Final Written Decision Finding Seagen Antibody-Drug Conjugate Patent Claims to be Unpatentable

On January 16, 2024, the Patent Trial and Appeal Board (PTAB) of the United States Patent and Trademark Office issued a **Final Written Decision** in a post-grant review (PGR) (PGR2021-00030) of claims in US Patent No. 10,808,039 (“the ’039 patent”) owned by Seagen. The PGR, filed by Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals, LP, requested review of claims 1-5, 9, and 10 of the ’039 patent, which are directed to antibody-drug conjugates (ADC) capable of intracellular cleavage. The ’039 patent is at issue in a patent infringement lawsuit brought by Seagen against Daiichi Sankyo over Daiichi’s FDA-approved ADC cancer therapy ENHERTU®. Previously, a federal jury has found that ENHERTU infringed the ’039 patent and awarded $41.8 million in royalty revenue to Seagen.

Issues raised in the PGR included whether claims 1-5, 9, and 10 of the ’039 patent were not patentable for lack of written description and enablement under 35 U.S.C. §112(a), indefiniteness under 35 U.S.C. §112(b), and anticipation under 35 U.S.C. §102.

On the issue of written description, Daiichi argued that the claims were not sufficiently supported because (a) the disclosure lacked descriptive support for the claimed gly/phe tetrapeptide component (W_w) of the ADC, and (b) the disclosure did not describe a representative number of species for the genus of “drug moiety” nor did the disclosure demonstrate common structural features for the “drug moiety” component.

On enablement, Daiichi argued that the ’039 patent does not enable the full scope of the claimed ADCs. Specifically, it noted that “[c]omplex chemical interactions among ADC components affect its structure and properties,” and that “[w]hile the claim does limit one aspect of the linker … the structural limitations of the claim still encompass an astronomical number of structurally and functionally disparate compounds.”

In the Final Written Decision, the PTAB held that claims 1-5, 9, and 10 are unpatentable for failing to comply with the written description and enablement requirements under Section 112(a).

Among its findings for written description, the PTAB determined that the specification of the ’039

patent did not have sufficient written descriptive support for claimed gly/phe tetrapeptide component. Noteworthy, with regards to the "drug moiety," the PTAB opinion distinguished the Seagen patent from the patent at issue in *Juno v. Kite*, stating that the '039 specification disclosed dozens of different known chemotherapeutic agents in multiple classes. Further, the opinion referred to *Falko-Gunter Falkner v. Inglis* in noting that "the recitation of known structures … 'would serve no goal of the written description requirement'." The opinion also stated that "the claims of the '039 patent are not focused on the particular cancer drugs selected from the large number of known cancer drugs or the antibody used, but rather focus entirely on the linker joining a drug moiety and an antibody or other ligand moiety."

The PTAB also found that the claims were not enabled. After going through the Wands Factors, the PTAB concluded that undue experimentation would have been required to make and use the claimed invention in view of, for example, the large scope of the ADC claims, the limited working examples and guidance provided by the patent, the unpredictability of the art around ADCs, and the quantity of experimentation needed. The claims were also found to be anticipated under Section 102.

Daiichi's general counsel issued a statement saying that the company is "pleased" with the PTO's decision. Seagen issued a statement indicating that it would appeal the decision.

Some Much-Needed (Applicant-Friendly) Clarification on Priority Claims at the European Patent Office

 On October 10, 2023, the Enlarged Board of Appeal of the European Patent Office (EPO) issued a **consolidated decision in cases G1/22 and G2/22** clarifying a common issue regarding the validity of a priority claim made at the EPO. **Per the Board of Appeal, there is a rebuttable presumption that an Applicant claiming priority is entitled to claim that priority**.

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Supreme Court Affirms Amgen Patents'

Invalidity in Closely Watched Enablement Case

 The U.S. Supreme Court has decided a closely watched case regarding patent law's enablement requirement, *Amgen Inc. v. Sanofi*. The Supreme Court affirmed the Federal Circuit's decision that Amgen's patent claims were invalid, holding that the patents' disclosures "offer[ed] persons skilled in the art little more than advice to engage in 'trial and error.'"

The Court's decision was unanimous. Although Amgen and various amici had urged the Court to adjust the standard for enablement in ways that would favor patent validity, the Court's decision announced no major changes to the doctrine.

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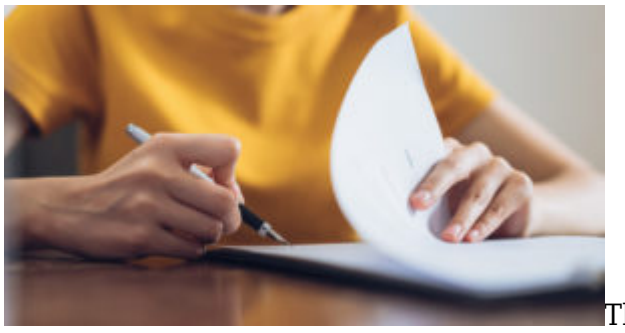
Proposed USPTO Fee Changes Will Make It Much More Expensive to Patent and to Challenge Patents on Therapeutics. You Have an Opportunity to Comment...

 The United States Patent & Trademark Office (USPTO or PTO) recently announced **proposed changes** to certain fees it charges with respect to patent applications, design patents, and America Invents Act (AIA) trials. These changes may significantly increase costs associated with building a robust patent portfolio for New Chemical Entities (NCEs) and Biologics, and to challenge patents at the PTAB. An oral hearing on the proposed changes will be held on **May 18, 2023**, and the USPTO is accepting written comments until **May 25, 2023**.

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NIH Again Refuses to Exercise March-In Rights to Control Drug Price

 In a letter dated March 21, 2023, the National Institutes of Health ("NIH") again refused the request of petitioners to exercise march-in rights under the Bayh-Dole Act to control the price of a drug. Here, as before, the NIH found that the statutory criteria for the use of march-in rights were not satisfied by the petitioners.

March-in rights can permit the government to require a patent owner to grant additional licenses to the invention to avoid situations such as a company licensing the technology but then not commercializing it. The Bayh-Dole Act enumerates the circumstances under which march-in rights and the grant of additional licenses are warranted, for example, to achieve practical application of the invention or to alleviate health and safety needs that are not being reasonably satisfied.

In November 2021, the Secretary of the Department of Health and Human Services ("HHS") received a petition from individuals Robert Sachs and Clare Love requesting the exercise of march-in rights under the Bayh-Dole Act to lower the price of the prostate cancer drug, Xtandi (enzalutamide). The patented drug product was invented at the University of California, Los Angeles, with funding from the NIH and U.S. Army. Xtandi, which is marketed in the United States by Astellas and Pfizer, costs more in the U.S. than it does elsewhere including other high-income countries. Petitioners argued that drug price can forbid access, specifically at prices that are allegedly unreasonable, contrary to the Bayh-Dole Act.

While the NIH's response letter expressed its concern about the high cost of drugs and the burden it places on patients, the letter explained the purpose of the Bayh-Dole Act is to promote the commercialization and public availability of government funded inventions. The overarching proposition of the Act is to permit recipients of federal government funding to retain ownership of patent rights and thereby commercialize the inventions by partnering with the private sector. Prior to the Bayh-Dole Act, most government funded inventions were not licensed or commercialized, including not one drug product.

The letter indicated that the NIH's analysis found that Xtandi is widely available to the public. The NIH stated that consistent with past march-in determinations in response to petitions for controlling drug prices, practical application of the invention is evidenced by practice of the invention and the invention's availability to the public. Astellas, the maker of Xtandi, estimated that more than 200,000 patients since 2012 were treated with the drug. Accordingly, the NIH concluded that the patent owner, the University of California, which licenses the patents to Astellas, meets the requirement for bringing Xtandi to practical application.

In addition, the NIH also stated that given the remaining patent life of the drug and the lengthy

administrative procedure for the exercise of march-in rights, the NIH does not believe that the use of march-in rights would be an effective way at lowering the cost of the drug. Therefore, for these reasons, the NIH determined that march-in rights were not warranted in this situation.

The letter ends stating that the NIH and HHS would pursue a "whole of government approach," informed by public input, to ensure the use of march-in rights is consistent with the Bayh-Dole Act, promotes commercialization of federally funded research, maximizes the potential for federally funded technologies to become products, and is in the interests of the American public. To that end, on the same day as the NIH letter, HHS and the Department of Commerce ("DOC") announced a plan to review march-in authority as found in the Bayh-Dole Act with these same goals.

The NIH decision is in line with the several other petitions that have been filed for other drugs over the last few decades as well as previous petitions involving Xtandi. The exercise of march-in rights by a federal agency likely would have a negative impact on companies developing products invented using federal funding if investors believe that the price of such products could be controlled by the federal government based on public input. We will continue to monitor developments in this area, including for any recommendations from the HHS and DOC inter-agency working group on this important topic.

USPTO Director Issues Precedential Review Decision Regarding Multiple Dependent Claims

Director Katherine Vidal of the U.S. Patent and Trademark Office ("USPTO") issued a precedential review decision with respect to the interpretation of multiple dependent claims, in a case of first impression before the Patent and Trial Appeal Board ("PTAB"). In the review of the PTAB's final written Decision and Order, the Director modified it consistent with her determination of the treatment of multiple dependent claims, which are claims that refer to and incorporate by reference more than one other claim.

More specifically, at issue in the *inter partes* review captioned, Nested Bean, Inc. v. Big Beings Pty Ltd., was the interpretation of 35 U.S.C. § 112, fifth paragraph, which is the controlling statute for multiple dependent claims. The Patent Owner contended that the statute requires the PTAB to consider the patentability of each claim referenced separately. In contrast, the Petitioner argued that if any claim of a multiple dependent claim is unpatentable, then the entire claim is unpatentable. For the reasons that follow, the Director agreed with the Patent Owner.

35 U.S.C. § 112, fifth paragraph, states in relevant part, "[a] multiple dependent claim shall be

construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered." The related Codified Rule, 37 C.F.R. § 1.75(c) states, in relevant part, "[a] multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered." With other statutes and Rules considered, the Director reasoned that the plain language of 35 U.S.C. § 112, fifth paragraph, conveys that a multiple dependent claim is the equivalent of several single dependent claims.

In addition to relying upon the applicable statute and Rules, the Director also considered Federal Circuit case law, legislative history, and USPTO procedure.

More specifically, with respect to precedent, neither party identified a judicial or administrative decision addressing the issue at hand. However, the Director found that Federal Circuit cases identified were supportive of the Patent Owner's position.

The Director found that USPTO guidance and procedures further supported the Patent Owner's interpretation. For example, the Manual for Patent Examining Practice (M.P.E.P.) advises examiners that "a multiple dependent claim must be considered in the same manner as a plurality of single dependent claims." M.P.E.P. § 608.01(n)(I)(B)(4).[1] Further, as the Director found, the USPTO claim fee structure is such that applicants must pay separately for each multiple dependent combination, e.g., for a multiple dependent claim that refers to three independent claims, the USPTO charges for three dependent claims.

Thus, after reviewing the PTAB's Decision and the relevant information, Director Vidal acknowledged that it was an issue of first impression before the Board. And based on the plain meaning of the statute, 35 U.S.C. § 112, fifth paragraph, requires that the patentability of a multiple dependent claim be considered separately with respect to each claim to which it refers. Accordingly, the Director's Review Decision modifies the PTAB's final written Decision and Order consistent with her interpretation of determining the patentability of multiple dependent claims, each separately as if multiple single dependent claims.

The Director's Review Decision clarifies the interpretation of U.S. patents containing multiple dependent claims and determining the patentability thereof. In particular, a patentee now knows that each claim of a multiple dependent claim should stand or fall by itself, independent of the invalidity of other dependent claims of the same multiple dependent claim.

[1] Eighth Ed., Rev. 7 (July 2008), which was the version in effect as of the earliest priority date of the relevant patent.

Decision Time: The Unified Patent Court Begins in 2023

 The Unified Patent Court ("UPC") is set to begin on June 1, 2023. Under the UPC framework, a single court proceeding could result in simultaneous revocation of European Patents across multiple European Union ("EU") countries, including France and Germany.

A three-month "Sunrise Period" is set to begin March 1, 2023. If a request is filed during the Sunrise Period, patent owners can "opt-out" specific patents from the UPC, such that they never become subject to the UPC unless the patent owner decides to withdraw the opt-out. However, the opt-out procedure is not necessarily straightforward. Importantly, if not done correctly ***and*** completed within the Sunrise Period, any patent challenged by a third party within the UPC will irrevocably be confined to the UPC's jurisdiction. Given the high stakes, patent owners should begin assessing which patents they would like to opt-out of the UPC and ensure that the necessary parties are involved in the opt-out procedure. Parties to license agreements, collaboration agreements, and the like should evaluate their existing agreements to see if they are UPC ready. Further, parties to future agreements should take the UPC into account when drafting those agreements.

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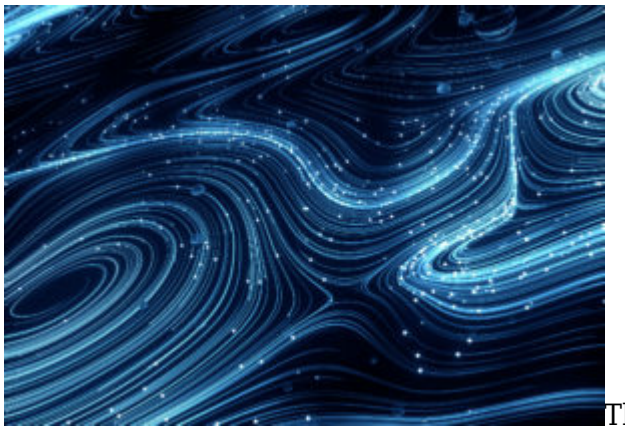
USPTO Announces Cancer Moonshot Expedited Examination Program

 The U.S. Patent and Trademark Office ("USPTO") published a Notice in the Federal Register announcing a new pilot program entitled, "Cancer Moonshot Expedited Examination Pilot Program" (the "Cancer Moonshot Program") (87 Fed. Reg. 75608 (December 9, 2022)) (the "Notice") to attempt to further accelerate innovation in the health and medical fields. Beginning on February 1, 2023, this new program will replace the Cancer Immunotherapy Pilot Program and expedite examination for a broader scope of technologies to prevent cancer and advance smoking cessation. The Cancer Moonshot Program is to support President Biden's recently renewed Cancer Moonshot initiative, which set a new goal of reducing cancer death rate by at least 50% over the next 25 years.

In contrast to the current Cancer Immunotherapy Pilot Program, which required the application to contain a claim to a method of treating a cancer using immunotherapy, the Cancer Moonshot Program covers a wider range of eligible technology areas. Under the new program, applications must be in the field of oncology or smoking cessation and must contain at least one of the following method claims (collectively, the "eligible method claims"):

1. A method of treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition (cancer immunotherapy related technology area);

2. A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition (personalized medicine related technology area);

3. A method of treating a rare or childhood cancer using a specific pharmaceutical composition (rare cancers related technology area);

4. A method of detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer (medical device related technology area);

5. A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer (diagnostic and treatment related technology area); and

6. A method of treating a nicotine dependency and promoting smoking cessation by administering a specific pharmaceutical composition (nicotine dependency and smoking cessation related technology area).

If the application contains "eligible" product or apparatus claims (i.e., claims to the immunotherapeutic compound or composition, the pharmaceutical composition, or the medical device used in an eligible method claim), the eligible method claims must depend from or be commensurate in scope with the eligible product or apparatus claims in the application (i.e., the eligible method claims must contain all of the limitations of the eligible product or apparatus claims).

The Notice details the requirements for petitions to make special under the Cancer Moonshot Program. For example, the application must be a nonprovisional utility patent application and contain no more than 3 independent and 20 total claims, with no multiple dependent claims. The claims must include at least one eligible method claim and a statement to that effect including that the application is limited to the field of oncology or smoking cessation. A statement must be filed indicating that special status was not previously granted for any reason for the application. In addition, a limitation exists on the number of times an inventor can file for special status under this program. Finally, a USPTO form must also be filed with the application, which form contains the necessary certifications for qualification to participate in the program.

Upon granting of the petition, the application will be treated as special on an examiner's docket and taken up out of turn for examination. The application will be accorded special status until a first Office action, which may be a restriction requirement. After the first Office action, the application will no longer be entitled to special status and will be taken up in a normal course on the examiner's docket. That is, after the first Office action, the application will undergo regular examination similar to all other applications.

The Notice indicates that the USPTO will periodically evaluate the Cancer Moonshot Program to

determine whether and to what extent its coverage should be changed.

Let's hope that this incentivization program provides a real impact on accelerating innovation in developing new treatments for cancer. And if interested in participating in the program, please contact a Goodwin patent lawyer.

USPTO and FDA Continue to Focus on Patent Quality in the Pharmaceutical Industry

 After a recent reminder from the U.S. Patent and Trademark Office (USPTO) regarding the duties of disclosure and reasonable inquiry during examination of a patent application and a Request for Comments (RFC) on the USPTO initiatives to ensure "robustness and reliability" of patent rights,[1] the Director of the U.S. Patent and Trademark Office published a third notice in less than four months. The latest notice is in conjunction with the Food and Drug Administration (FDA) to further the discussion surrounding the patent practices of the pharmaceutical industry (**87 Fed. Reg. 67019** (November 7, 2022)). Specifically, the notice is of a public listening session and request for comments (PLS/RFC).

Against the backdrop of President Biden's Competition Executive Order (EO) that calls for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law," as well as Congressional and public interest in this goal, the stated purpose of the present notice of the PLS/RFC is to obtain public input for areas of joint USPTO-FDA collaboration and engagement with respect to the pharmaceutical industry to promote greater access to medicines for American families.

In particular, the USPTO and FDA are seeking feedback from a broad group of stakeholders, most notably, patients and their caregivers, patient advocates, representatives from regulated industry, including companies that sell branded medicines, generic drugs and biosimilars, healthcare organizations, payers and insurers, academic institutions, public interest groups, and the general public.

The background of the notice of the PLS/RFC describes the response to the EO and details certain communications between the USPTO and the FDA in furtherance of its objectives. More specifically, in a letter from the USPTO to the FDA, initiatives for collaboration were outlined including exploring joint USPTO-FDA public engagements, providing examiners with training on publicly available FDA resources, exploring consistency in representations made to the USPTO and the FDA, revisiting patent term extension (PTE) practice, exploring the policies surrounding the use of "skinny labels," and being open to discussing "patent thickets," "evergreening," and "product hopping."

Further, in the current notice, the USPTO states in a footnote that this collaborative PLS/RFC is in parallel with the USPTO's initial RFC. The initial RFC included new USPTO initiatives to advance the EO; such initiatives include seeking input on enhancing processes for information disclosure statements and the identification of key prior art, considering applying greater scrutiny to continuation patent applications and use of declaratory evidence during patent prosecution, revisiting terminal disclaimer practice and procedures for third party input during prosecution, and conducting a comparative analysis of the prosecution and grant of "pharmaceutical and biological patents" in the United States versus other countries.

Although the USPTO notice on disclosure requirements and the initial RFC include all technologies, it is clear that the focus of the USPTO/FDA's inquiries are related to the pharmaceutical and biologics industries.

More specifically, with respect to the PLS/RFC, its inquiries include considering what FDA resources may be available to USPTO examiners to assess patentability, e.g., determining whether inconsistent statements were made to the USPTO and the FDA, using AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, revisiting PTE practices, understanding "skinny label" practice, and generally promoting greater availability of generic products. The PLS/RFC also seeks input on the questions posed in the USPTO letter to the FDA mentioned above.

The in-person PLS at the USPTO is scheduled for January 19, 2023, from 10 am to 5 pm (ET), for which preregistration is needed to speak. Written comments to the PLS/RFC will be accepted until February 6, 2023, with the comments to the initial RFC of the USPTO extended until February 1, 2023.

Stakeholders are encouraged to participate and we will monitor how the USPTO and the FDA respond to these hotly debated topics that impact almost every American.

[1] See **87 FR 45764** (July 29, 2022) and **87 FR 60130** (October 4, 2022), respectively. See also ***USPTO Publishes Notice Calling Out Pharmaceutical Industry***, Goodwin Life Sciences Perspective blog, July 29, 2022; and ***USPTO Doubles Down Calling Out Pharmaceutical Industry***, Goodwin Life Sciences Perspective blog, October 19, 2022, respectively.