
MAYER | BROWN
PATENT TERM EXTENSION
FOR FDA-APPROVED PRODUCTS

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George works with life sciences companies of all sizes to assist them in developing and marketing innovative products that are regulated by the US Food and Drug Administration, including drugs and biologics, medical devices, drug-device combination products, CBD and botanical products, medical foods and dietary supplements.

George has deep experience providing regulatory advice to pharmaceutical and biotech companies on lifecycle management issues, including regulatory exclusivities and FDA-facing patent issues. He is a leading expert on orphan drug matters, including orphan designation and exclusivity, and has successfully advocated on behalf of clients to FDA on matters related to prevalence, orphan subsets, and clinical superiority. George also regularly advises pharmaceutical and biotechnology companies on pediatric study and pediatric exclusivity issues arising under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

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Vera works with like science clients to align their IP and regulatory strategies to maximize the value and exclusivity of their products. A Registered Patent Attorney, Vera develops global patent and lifecycle management strategies for prescription and OTC drugs, medical devices and biologics.

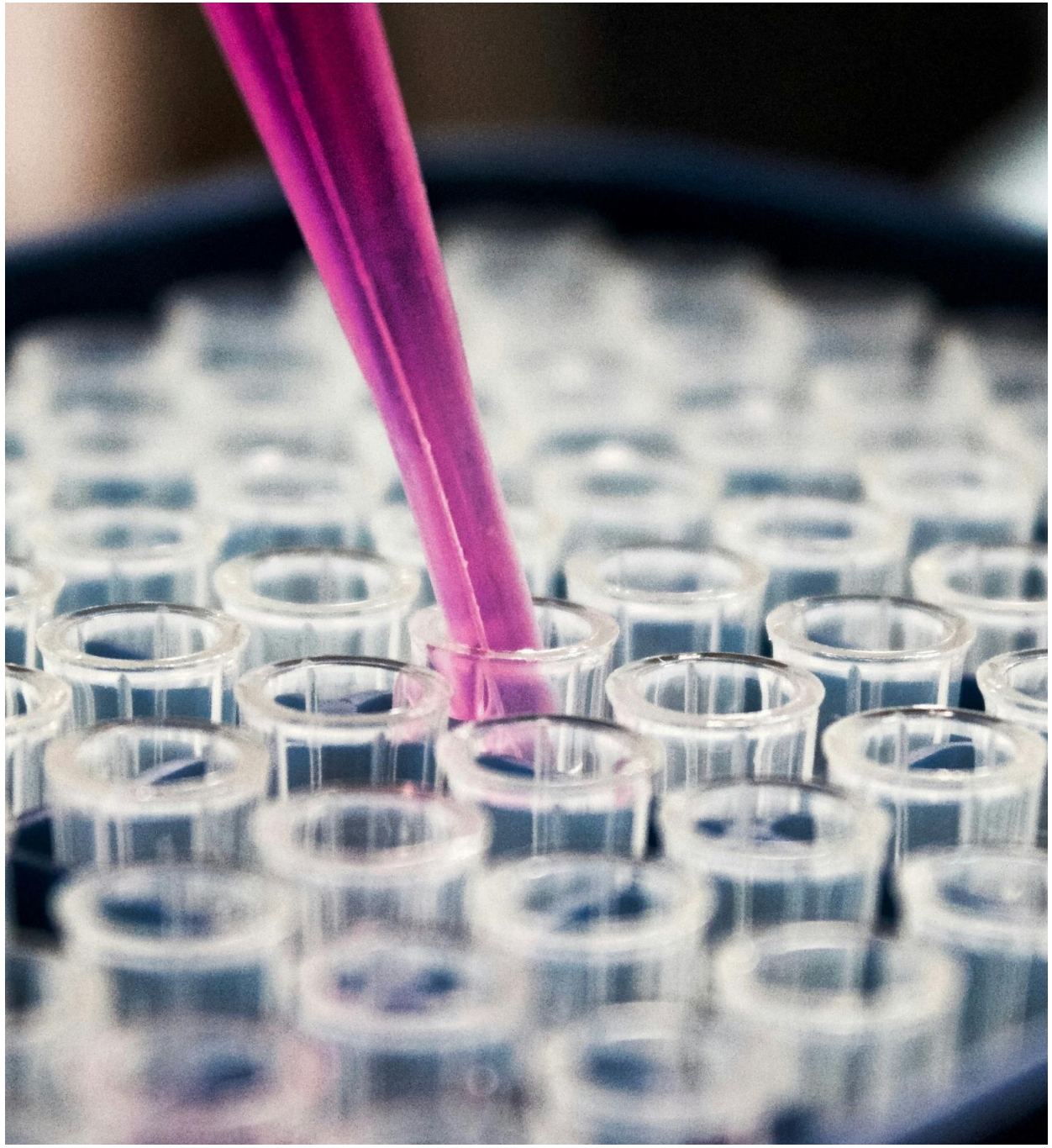
Vera also evaluates, structures and manages the IP and regulatory assessments of commercial transactions, including IP due diligence for stock and asset acquisitions, divestitures, mergers, and strategic alliances involving US, foreign and multinational corporations. She drafts and negotiates patent licenses, joint venture and collaboration agreements, and product distribution agreements.

AGENDA

1. Overview of Patent Term Extension (PTE) Regime
2. Qualifying for PTE
3. Submitting a PTE Application
4. Review of the PTE Application
5. Calculating the PTE Award
6. Miscellaneous Issues

PATENT TERM EXTENSION: A BRIEF OVERVIEW

- The purpose of PTE is to restore some portion of the patent term "lost" during the clinical development process and review by the Food and Drug Administration (FDA)
  - Part of the Hatch-Waxman Act's grand bargain, giventhe unique regulatory regime governing commercialization of FDA-approved products
- The US Patent and Trademark Office (USPTO) administers the PTE regime, but collaborates closely with FDA
- Eligible products are those that have been subject to a "regulatory review period" prior to commercialization
  - Drugs, biologics, medical devices will be the focus of today's webinar
  - New animal drugs, veterinary biological products, food additives, and color additives are also eligible



Qualifying for PTE

ELIGIBILITY FOR PTE: THE LEGAL STANDARD

- Under 35 USC 156(a), "the term of a patent which claims ***a product, a method of using a product, or a method of manufacturing a product*** shall be extended in accordance with this section from the original expiration date of the patent, which shall include any patent term adjustment…," if certain conditions are met:
  1) the ***patent term has not expired*** before a PTE application is submitted;
  2) the ***patent term has never been extended*** under this section;
  3) an ***application*** for PTE is ***submitted by the owner of record of the patent or its agent***;
  4) the ***product has been subject to a "regulatory review period" before its commercial marketing*** or use; and
  5) subject to exceptions for certain animal drugs/veterinary biologics, the permission for the commercial marketing or use of the product after such regulatory review period is ***the first permitted commercial marketing or use of the product***.
- Generally, the application of these criteria are straightforward.
- However, issues have arisen regarding the definition of the "product" at issue and whether FDA approval of that product represents the first permitted commercial marketing

WHAT IS THE "PRODUCT" FOR PURPOSES OF PTE?

- "Product" is defined as:
  - A "drug product," or
  - Any medical device, food additive, or color additive subject to regulation under the Federal Food, Drug, and Cosmetic Act (FDCA)
- "Drug product" is further defined in the statute and regulations to mean:
  - "The active ingredient of a new human drug, antibiotic drug, or human biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act)…. including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient…." 35 USC 156 (f)(2); 37 CFR 1.710(b)(1).
- The USPTO will look at the active ingredient in the finished drug product prior to administration. *See Hoechst-Roussel Pharms. v. Lehman*, 109 F.3d 757, 759 n.3 ("For purposes of patent term extension, this active ingredient must be present in the drug product when administered.")

ISSUES ARISING FROM THE DEFINITION OF "DRUG PRODUCT": THE *PHOTOCURE* CASE

- Eligibility for PTE often aligns with eligibility for 5-year "new chemical entity" (NCE) exclusivity for novel drug products submitted in new drug applications (NDAs), but ***some products can obtain PTE even if not eligible for NCE exclusivity***
  - For purposes of NCE exclusivity, FDA focuses on the "active moiety" of the drug product by excluding any salt or ester appendages of the active ingredient.
    - That active moiety is then eligible for NCE exclusivity if it has not previously been approved in another NDA
  - The USPTO previously sought to apply a similar "active moiety" standard, but that interpretation was found to be impermissible in *Photocure v. Kappos,* 603 F.3d 1372 (Fed. Cir. 2010).
    - Instead, PTO will now look only at the active ingredient and ask three questions:
      1) Has the active ingredient been previously approved?
      2) Has a salt of the active ingredient been approved?
      3) Has an ester of the active ingredient been approved?
    - A "yes" to any of these questions means that the approval of the product does not represent the first permitted commercial marketing – and the product is not eligible for PTE.

IMPLICATIONS OF THE *PHOTOCURE* CASE

- In *Photocure*, the USPTO initially sought to deny PTE based on the 2004 FDA approval of Photocure's METVIXIA (methyl aminolevulinate hydrochloride)
  - Methyl aminolevulinate hydrochloride (MAL Hcl) is the methyl ester of aminolevulinic acid hydrochloride (ALA Hcl), which is the active ingredient of a product, LEVULAN, that had been approved by FDA in 1999.
  - As a result, FDA did not grant NCE exclusivity to METVIXIA, because its active moiety is the same as that in LEVULAN.
  - The USPTO initially denied PTE for METVIXIA on the basis that its approval did not represent the first permitted commercial marketing of the product, which it considered to be the active moiety.
- Photocure prevailed in litigation, and the court focused on the statutory language defining "drug product," which is defined in relevant part as the "active ingredient of a new human drug…including any salt or ester of the active ingredient."
  - Here, ALA Hcl (the previously approved active ingredient) was not the same active ingredient as MAL Hcl, nor was ALA Hcl a salt or ester of MAL Hcl.
  - Thus, MAL Hcl is the first permitted commercial marketing of the product → PTE awarded, despite no NCE exclusivity
  - If the order were different (ester form approved first, then non-esterified molecule), PTE would have been denied ("reverse *Photocure*")

ISSUES ARISING FROM THE DEFINITION OF "DRUG PRODUCT": COMBINATION PRODUCTS

- Combination products – *i.e.*, drug products that contain two or more active ingredients in a single dosage form – are eligible for PTE, in the following scenarios:
  1) None of the active ingredients have previously been approved (nor any salt or ester of those active ingredients),

     OR

  2) At least one of the active ingredients has not previously been approved (nor any salt or ester of that active ingredient) **AND** the patent claims the newly-approved active ingredient.
- A "new" combination of two previously approved active ingredients is **NOT** eligible for PTE. *See In re Alcon Laboratories Inc.*, 13 USPQ2d 1115, 1121 (Comm'r Pat. & Tm. 1989).
  - Approval of Tobradex (tobramycin; dexamethasone) not eligible for PTE, because both tobramycin and dexamethasone had previously been approved by FDA.
  - Synergistic effect of multiple active ingredients is irrelevant for this analysis. *Arnold Partnership v. Dudas*, 362 F.3d 1338 (Fed. Cir. 2004).
- BUT: PTE is available for a product containing an enantiomer of a previously approved racemate. *See Ortho-McNeil Pharm. v. Lupin Pharms,* 603 F.3d 1377 (Fed. Cir. 2010).

HAS THE PRODUCT BEEN SUBJECT TO A REGULATORY REVIEW PERIOD? DRUGS AND BIOLOGICS

- The "regulatory review period" is separately defined in the PTE statute for different classes of products.
  - In each case, the regulatory review period is defined as the sum of two periods, which are commonly referred to as a "Testing Phase" and an "Approval Phase."
- Drug or biological product:
  - Testing Phase: begins on the date an investigational new drug (IND) application became effective (typically 30 days after submission) and ends on the date a marketing application is submitted.
    - Marketing application incudes an NDA or a biologics license application (BLA).
    - If more than one IND has been opened for the same active ingredient, the earliest IND effective date is the relevant one.
  - Approval Phase: begins on the date the NDA or BLA is "initially submitted" and ends on the date the marketing application is approved.

HAS THE PRODUCT BEEN SUBJECT TO A REGULATORY REVIEW PERIOD? MEDICAL DEVICES

- Medical device product:
  - Testing Phase: begins on the date an investigational device exemption (IDE) became effective, or the date on which "a clinical investigation on humans…was begun" (if no IND), and ends on the date "on which the application for product approval or notice of completion of a product development protocol under Section 515 of the [FDCA] was initially submitted."
    - Section 515 of the FDCA describes the Premarket Application (PMA) process.
    - Thus, no PTE is available for medical device products "cleared" under Section 510(k) of the FDCA.
  - Review Phase: begins on the date the PMA was submitted and ends on the date that application was approved.

DOES FDA APPROVAL OF THE PRODUCT REPRESENT ITS "FIRST PERMITTED COMMERCIAL MARKETING"?

- This prong of the eligibility criteria asks whether "the permission for the commercial marketing or use of the product after such regulatory review period is the first permitted commercial marketing or use of the product."
  - Typically easy to apply: has FDA previously approved the same "product" under the same type of "regulatory review period"?
- However, several issues have arisen under this criterion:
  - Different statutory authorities = different regulatory review periods
    - For example, a product approved first as a human drug product under an NDA and subsequently approved as an animal/veterinary drug under a "new animal drug application" (NADA) is eligible for PTE for both approvals, because the regulatory review period for each occurred under a different statutory authority.
  - Multiple NDAs or BLAs approved on the same day
    - USPTO's approach has been evolving (somewhat surreptitiously)
    - More on this on the next slide

FIRST PERMITTED COMMERCIAL MARKETING: TWO OR MORE SIMULTANEOUS APPROVALS

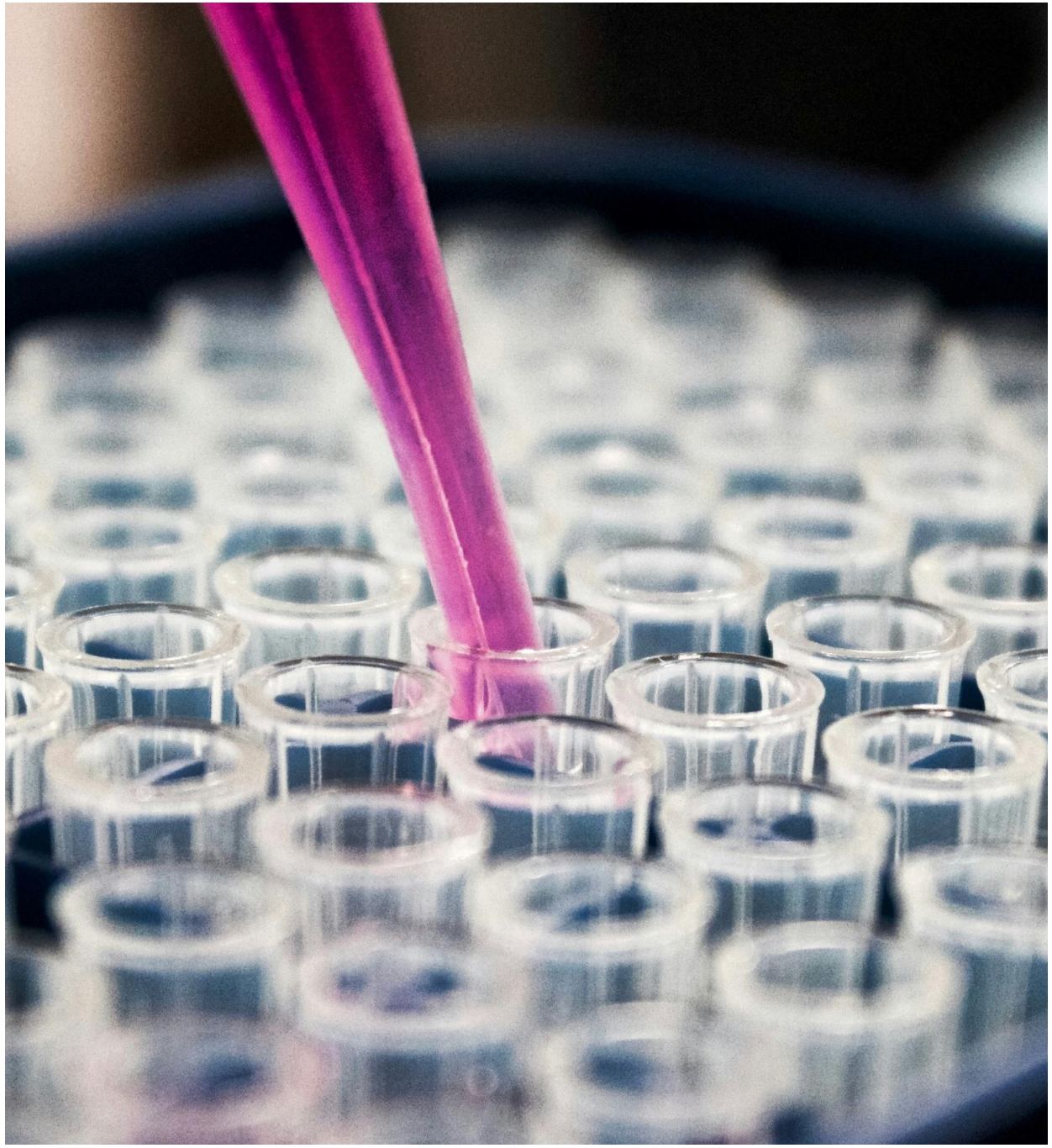
- Under 35 USC 156(c)(4), only a single patent may be extended "for the same regulatory review period for any product."
- Similarly, under 35 USC 156(a)(5), the approval of the product must represent the "first permitted commercial marketing or use of the product."
- If multiple NDAs or BLAs covering the same drug or biological product are approved on the same day, the USPTO and FDA have historically determined that multiple patents could be extended under PTE because ***both*** NDAs or BLAs represented the "first permitted commercial marketing" and different regulatory review periods.
  - This can arise when, *e.g.*, approval is sought for two different indications or two different dosage forms.
  - For example, in 2007 FDA approved two NDAs for LYRICA (pregabalin) on the same day. The USPTO granted extensions for two patents, one for each NDA.
  - In 2016, PTO granted three extensions based on the same-day approval of three NDAs for products containing the active ingredient alogliptin.

– Beginning in approximately 2020, PTO has sought to change its position in the context of individual PTE applications:
  - The USPTO stated: "Although both FDA approvals received the same date, they cannot both be considered as 'first' approved under § 156(a)(5)(A) and they cannot both constitute distinct regulatory review periods under § 156(a)(4)…."

Submitting a PTE Application

SUBMITTING A PTE APPLICATION

- The PTE application is ~20-page submission with multiple exhibits
- Plan ahead
  - Timing is critical
  - Most of the application can be done before FDA approval
- Applications must be submitted by owner of record of the patent
  - If different from the NDA/BLA holder, PTE applicant must obtain authorization to rely on efforts of NDA/BLA holder.
- Applications are made public via USPTO Patent Center and www.Regulations.gov



STRATEGIC CONSIDERATIONS

- PTE applications benefit from collaboration between IP and regulatory
- PTE applications can be submitted for multiple patents, although only one patent will be awarded PTE
  - The USPTO permits an applicant to select the patent to be awarded PTE at the end of the process
  - This allows applicants to defer identifying the strongest patent to use for PTE
- Consideration of PTE during licensing transactions
  - Who controls the PTE application and takes the lead on submitting?
  - Platform technologies and multiple licensees
  - Think ahead about the process, which can require collaboration between patent owner and NDA holder

TIMING OF PTE APPLICATION SUBMISSION

- PTE applications must be submitted in writing to the USPTO within 60 days of FDA's approval of the product.
- This issue arose in the context of an application filed by The Medicines Company (MDCO), which received its FDA approval letter by fax at 6:17 pm on Friday, December 15, 2000.
  - FDA published the approval date as "December 19, 2000" on its website.
  - MDCO submitted its PTE application on February 14, 2001 – 61 days after the faxed approval, but 58 days after the next business day.
  - After years of legal wrangling and lobbying, MDCO ultimately prevailed.

    "For purposes of determining the date the product received permission under the provision of law under which the applicable regulatory review period occurred for commercial marketing or use, if such permission is transmitted after 4:30 P.M., Eastern Time, on a business day, or is transmitted on a day that is not a business day, the product shall be deemed to have received such permission on the next business day." Manual of Patent Examining Procedure § 2754.01.

– **DON'T WAIT** until Day 60 (or even 58)

TIMING OF PTE APPLICATION SUBMISSION: CONTROLLED SUBSTANCES

- NDAs or BLAs for drug products containing controlled substances must await scheduling from the Drug Enforcement Administration (DEA) before commercial marketing can begin, ***even if FDA has granted final approval to the product***.
  - Pursuant to 35 USC 156(i), a "drug product for which the Secretary intends to recommend controls under the [Controlled Substances Act]…shall be considered to … have permission for commercial marketing or use" on the "covered date." In relevant part, the "covered date" means "the later of—

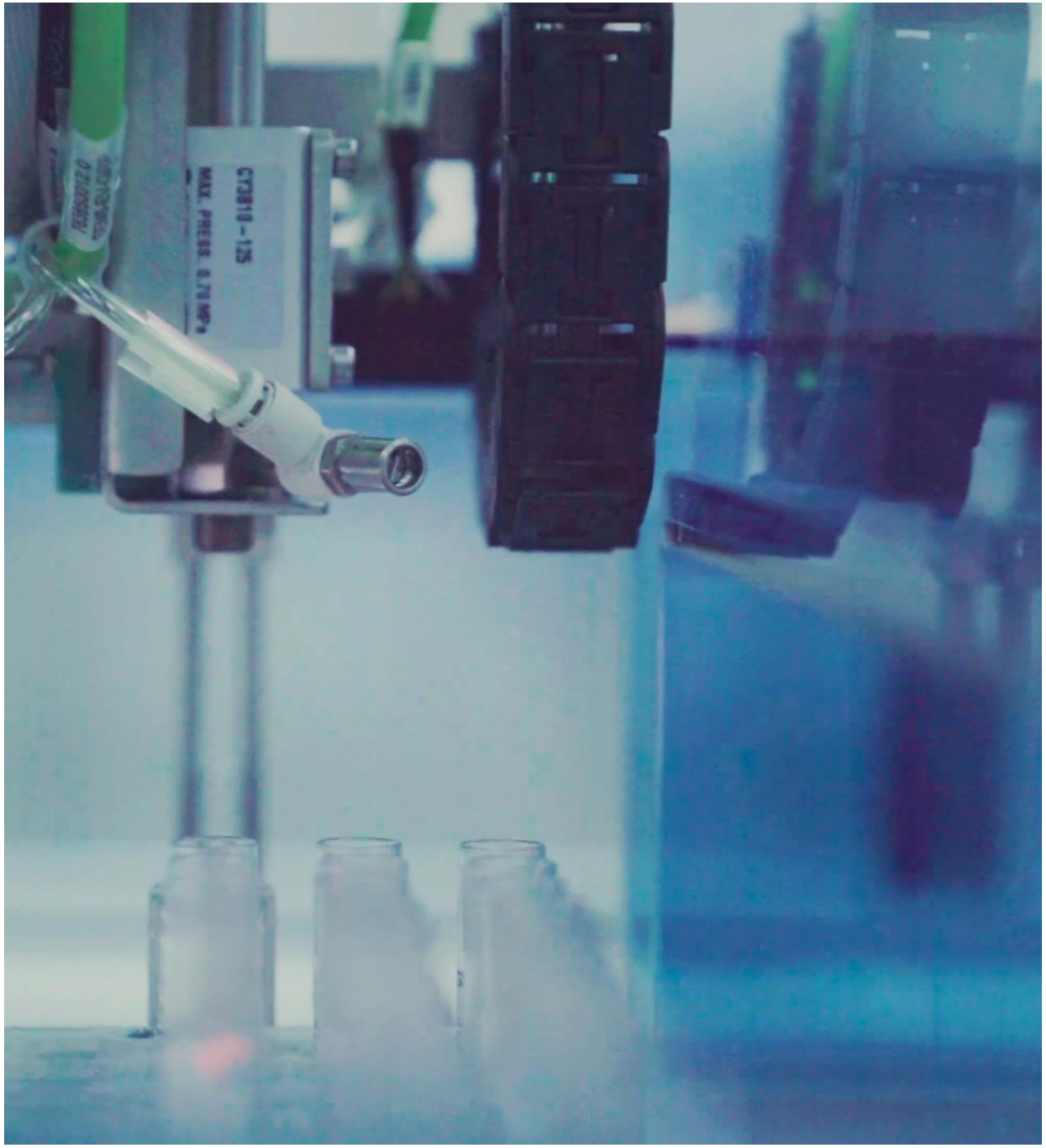
    the date an application is approved … under section 505(b) … of the Federal Food, Drug, and Cosmetic Act; … or the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act."
  - Generally, the scheduling order will come after the FDA approval, and thus the PTE application should be filed within 60 days of the scheduling order.
- This will also have implications for calculation of the regulatory review period for such products.

CONTENTS OF A PTE APPLICATION

1) Identification of the approved product (*i.e.*, appropriate chemical and generic name, physical structure or characteristics);
2) Identification of the statutory authority under which the regulatory review occurred (*i.e.*, Section 505 of the FDCA for NDAs);
3) Identification of the date on which the product received regulatory approval for commercial marketing or use;
4) In the case of a drug product, an identification of each active ingredient in the product and a statement that each active ingredient has not been previously approved for commercial marketing or use;
5) A statement that the PTE application is timely submitted within the 60-day period following FDA approval;

CONTENTS OF A PTE APPLICATION

6) Identification of the patent for which PTE is being sought;
7) A copy of the patent for which PTE is being sought;
8) A copy of any terminal disclaimer, certificate of correction, maintenance fee statement, or reexamination certificate;
9) A statement that the patent claims the approved product, or a method of using or manufacturing the approved product, and a showing for at least one claim how it reads on the product;
10) The relevant dates and information to enable determination of the applicable regulatory review period;
    - For a patent claiming a human drug or biological product, this includes:
        - The effective date of the IND application and the IND number;
        - The submission date of the NDA or BLA, and the NDA or BLA number; and
        - The approval date of the NDA or BLA.



CONTENTS OF A PTE APPLICATION

11) A brief description of the significant activities undertaken by the marketing applicant, and relevant dates, during the regulatory review period;

12) A statement that, in the applicant's opinion, the patent is eligible for PTE, including the length of the extension and how it was calculated;

13) A statement that applicant acknowledges the duty to disclose any information material to the determination of entitlement of the extension sought;

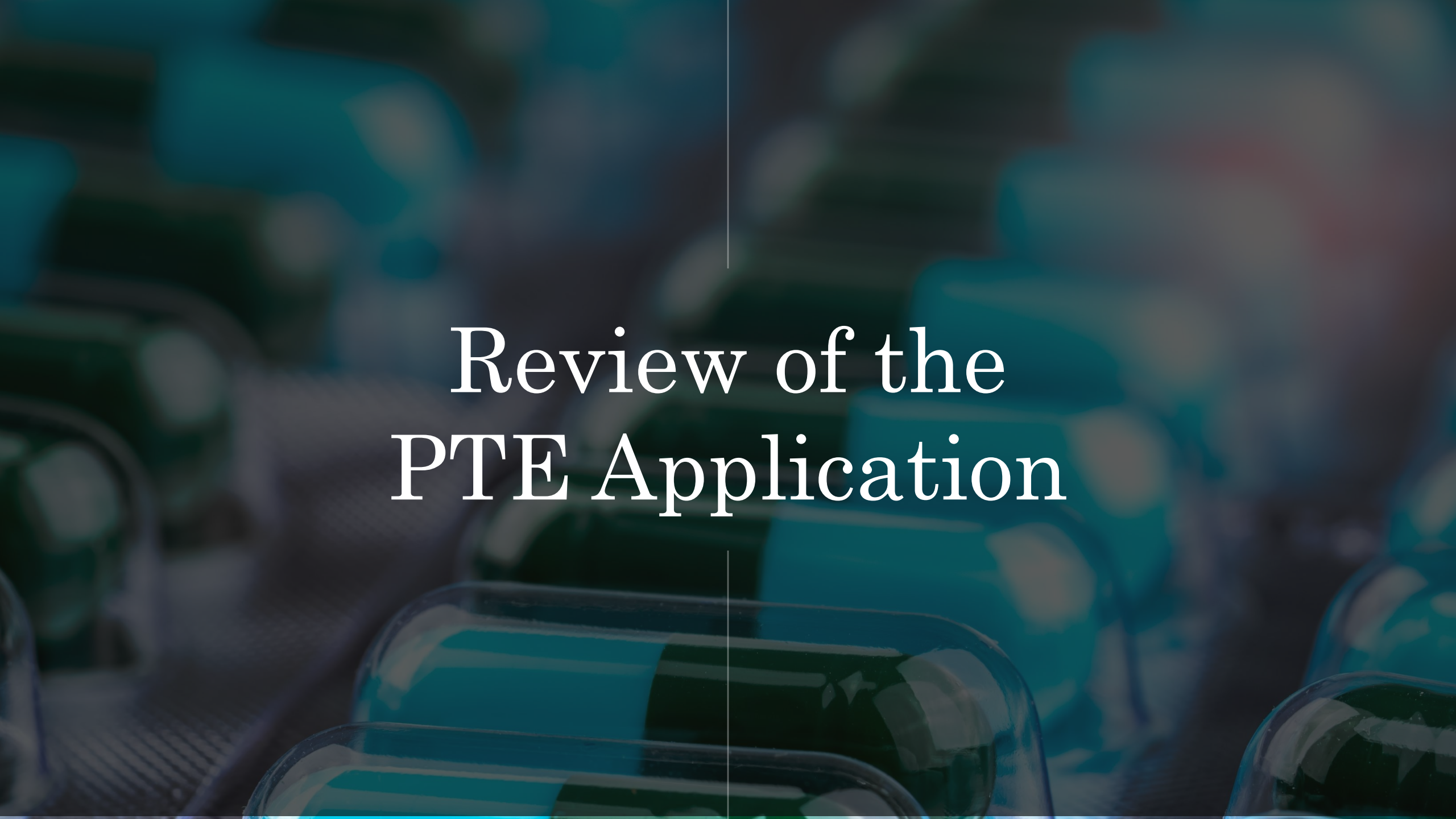
14) Payment of fees; and

15) Contact information of the person to whom correspondence relating to the PTE application is to be directed.

(Review 37 CFR 1.740 and MPEP § 2753 for further information.)

KEY ASPECTS OF THE PTE APPLICATION

- Common exhibits:
  - IND submission acknowledgment date letter
  - NDA/BLA submission acknowledgment letter
  - NDA/BLA approval letter
  - Copy of the patent
  - Terminal disclaimer, certificate of correction, maintenance fee statement, and/or reexamination certificate, as applicable
  - A "brief description of the significant activities undertaken by the marketing applicant…during the regulatory review period"
  - Authorization from NDA/BLA holder, if necessary
- The "brief description" document is typically a chronological log of correspondence between applicant and FDA, beginning with IND submission
  - Does not need to be an affirmative demonstration of due diligence
  - Gaps in development are common (more on this later)



Review of the PTE Application

REVIEW AND APPROVAL OF PTE APPLICATIONS INVOLVE BOTH THE USPTO AND FDA

- The USPTO and FDA each play a role in determining PTE eligibility and the length of the extension. *See* Memorandum of Understanding 225-86-8251 (Sept. 17, 1986).
  - The USPTO is ultimately responsible for awarding PTE, but relies on FDA for confirmation of certain facts and calculation of regulatory review period (RRP).
- Upon receipt of a PTE application, the USPTO performs an initial review:
  - ***Of the PTE application itself*** for compliance with 37 CFR 1.740(a)(1)-(15), which sets forth the formal requirements for a PTE application; and
  - ***Of the subject matter of the patent claims*** for compliance with 35 USC 156(a) and eligibility:
    - Only patents claiming (1) a product, (2) a method of using a product, or (3) a method of manufacturing a product are eligible.
- Then, an extended back-and-forth exchange of correspondence occurs between the agencies.
  - Although the statute provides relatively short timelines for at least part of this exchange, the two agencies are taking increasingly long to get through PTE applications.
  - It's not uncommon for PTE applications to be pending more than 4 years!

INITIAL EXCHANGES BETWEEN THE USPTO AND FDA

- PTO sends letter to FDA enclosing the PTE application and asks FDA to confirm that:
  - The product was subject to a qualifying regulatory review period prior to approval;
  - The permission to commercially market or use the product is the first permitted commercial marketing or use for the product; and
  - The PTE application was timely submitted within 60 days of the date of regulatory approval of the product.
- FDA opens a public docket on www.Regulations.gov and responds in writing to USPTO.
- Assuming FDA's response confirms eligibility, the USPTO then asks FDA to determine the length of the regulatory review period (RRP)
  - FDA does so in a letter back to the USPTO and also publishes its RRP determination in a Federal Register (FR) Notice, which will contain relevant dates and the total length of the RRP.
  - Publication of the FR Notice triggers two additional procedures and timelines for petitions regarding the RRP.

EXAMPLE OF A FEDERAL REGISTER NOTICE WITH FDA'S RRP DETERMINATION

Based on a review of the information collection, we have retained the currently approved burden estimate.

Dated: November 12, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2021–25294 Filed 11–18–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–E–5389]

Determination of Regulatory Review Period for Purposes of Patent Extension; SUNOSI

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for SUNOSI and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and

information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with § 10.20 (21 CFR 10.20) and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for SUNOSI is 8,209 days. Of this time, 7,664 days occurred during the testing phase of the regulatory review period, while 545 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* December 27, 1996. The applicant claims that December 17, 2009, is the date the investigational new drug application (IND) 107203 became effective. However, FDA's records indicate that the effective date was December 27, 1996. which was 30 davs after FDA receipt of the applicant's earlier IND 52082.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 20, 2017. FDA has verified the applicant's claim that the new drug application (NDA) for SUNOSI (NDA 211230) was initially submitted on December 20, 2017.

3. *The date the application was approved or the date of issuance of the interim final rule controlling the drug under section 201(j) of the Controlled Substances Act:* June 17, 2019. FDA has verified the applicant's claim that NDA 211230 was approved on March 20, 2019, and that the Drug Enforcement Administration issued an interim final rule controlling the product on June 17, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,386 days of patent term extension.

PETITIONS REGARDING FDA'S RRP DETERMINATION

- Following publication of FDA's RRP determination in the Federal Register, there are two petitions which may be filed:
  - **21 CFR 60.24**: Any person, including the PTE applicant, may seek reconsideration of the RRP determination.
    - Such petitions must be filed within 60 days of FR Notice.
  - **21 CFR 60.30**: Any person may submit a petition alleging that the marketing applicant did not act with due diligence in seeking FDA approval during the RRP.
    - Such petitions must be filed within 180 days of FR Notice.
    - The term "due diligence" is defined in 35 USC 156(d)(3) as "that degree of attention, continuous directed effort, and timeliness as may reasonably be expected from, and are ordinarily exercised by, a person during a regulatory review period."
  - FDA regulations contain detailed procedural provisions regarding these two petitions.
  - ***We are not aware of any "due diligence" petitions resulting in reduction of the RRP by FDA.***
- These petitions represent the only opportunity for third parties to engage regarding a PTE application.

FINAL EXCHANGES BETWEEN THE USPTO AND FDA

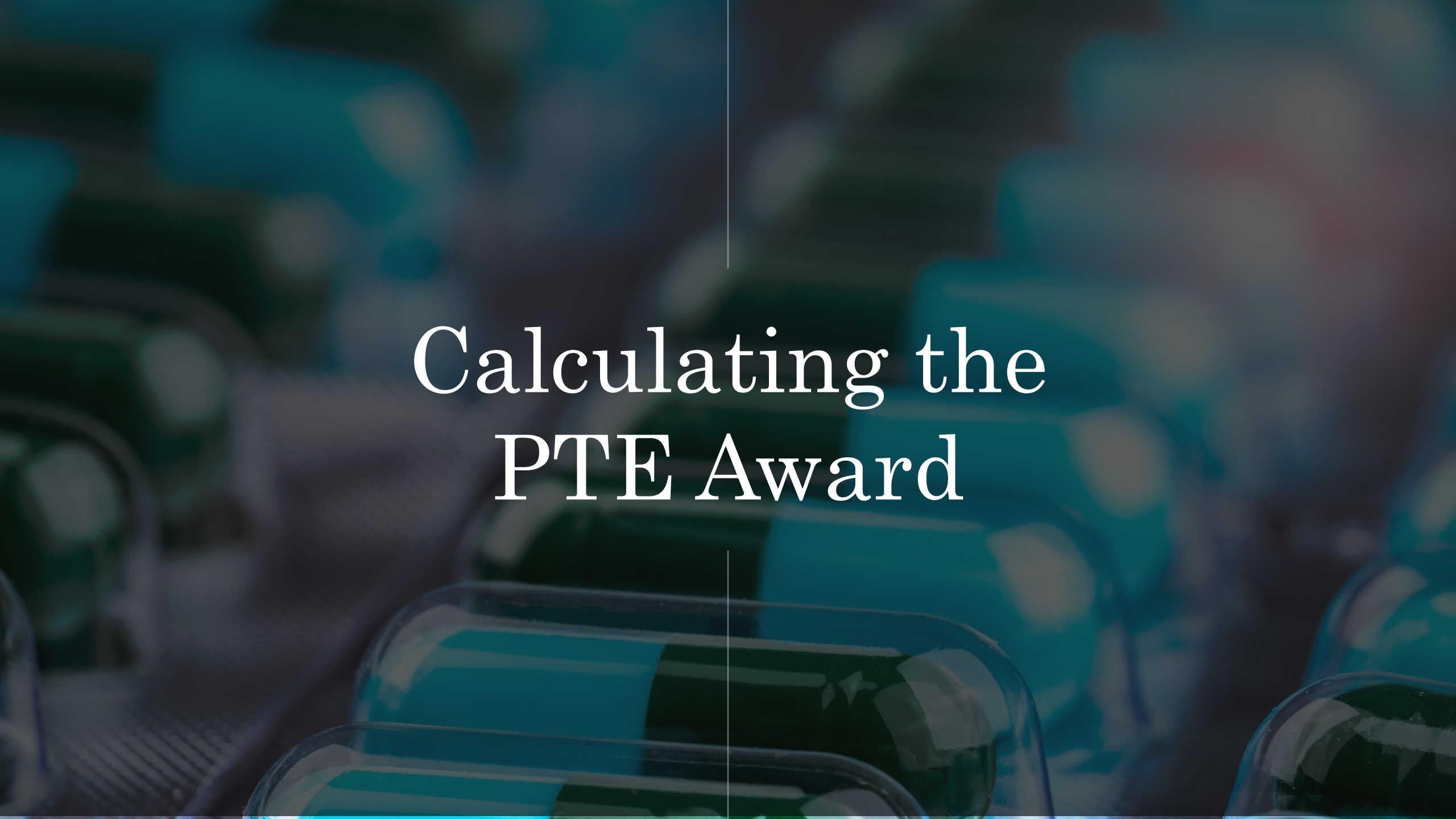
- Assuming no change in the RRP based on a petition under 21 CFR 60.24 or 21 CFR 60.30, FDA sends a letter to the USPTO stating that FDA's RRP determination is final.
  - The USPTO then determines the length of the final PTE award and issues a Notice of Final Determination.
  - The PTE applicant is given 1 month to request reconsideration of the calculated PTE award.
  - If multiple PTE applications were filed for the same approved NDA or BLA, the USPTO also asks the PTE applicant to identify the single paten for extension (and the other PTE applications will be withdrawn).
- Finally, the USPTO will issue a Certificate of Extension of Patent Term.

DELAYS AT USPTO AND FDA

- ***This process is taking several years at a minimum.***

– An illustrative example chosen at random:
  - February 2019: PMA approval
  - April 2019: PTE application submitted
  - July 2019: USPTO files initial letter to FDA
  - January 2020: FDA responds to USPTO
  - August 2020: USPTO asks FDA to determine RRP
  - July 2023: FDA publishes RRP determination in Federal Register
  - March 2024: FDA letter to USPTO finalizing RRP

– Still pending 5 years later!



Calculating the PTE Award

FDA REGULATORY REVIEW PERIOD DETERMINATIONS

- In determining the length of the Regulatory Review Period, the FDA reviews its records and provides the USPTO with:
  - Confirmation of the three key dates:
    - The start date of the Testing Phase, *i.e.*, the IND effective date
    - The date an application (NDA/BLA) was submitted to the FDA for regulatory approval
    - The date the NDA/BLA was approved
  - Calculation of the RRP:
    - The length of the Testing Phase
    - The length of the Approval Phase
      - For controlled substances, the length of the Approval Phase also includes the time after FDA grants approval and through the date (inclusive) that the DEA issues an interim scheduling order.
    - The total length of the Regulatory Review Period
- FDA approaches this in a very objective way and makes any necessary corrections to PTE applicant's assertions based on agency files.

CALCULATING THE PATENT TERM EXTENSION

- The final PTE award is determined by first calculating the drug product's "Regulatory Review Period" and then applying several statutory reductions and limitations.
- As noted above, FDA determines the "Regulatory Review Period" (RRP) = "Testing Phase" + "Approval Phase"
  - "Testing Phase" = IND effective date to NDA/BLA submission date
  - "Approval Phase" = NDA/BLA submission date to NDA/BLA approval date
- The USPTO applies several statutory limitations and deductions to calculate the final length of the PTE award:
  - Potential reductions of RRP:
    - Reduction for portion of the regulatory review period that occurred on or before the date the patent was issued
    - Reduction for lack of diligence, if FDA made such a finding pursuant to a petition under 21 CFR 60.30
    - Reduction of one-half of the Testing Phase
  - Limitations applied following reductions of RRP:
    - 5-year limit: the maximum PTE award is capped at 5 years
    - 14-year limit: the extended term of the patent cannot exceed 14 years from date of FDA approval

THE USPTO'S PTE EQUATION

Period of Extension = RRP - PGRRP - DD - ½(TP - PGTP)

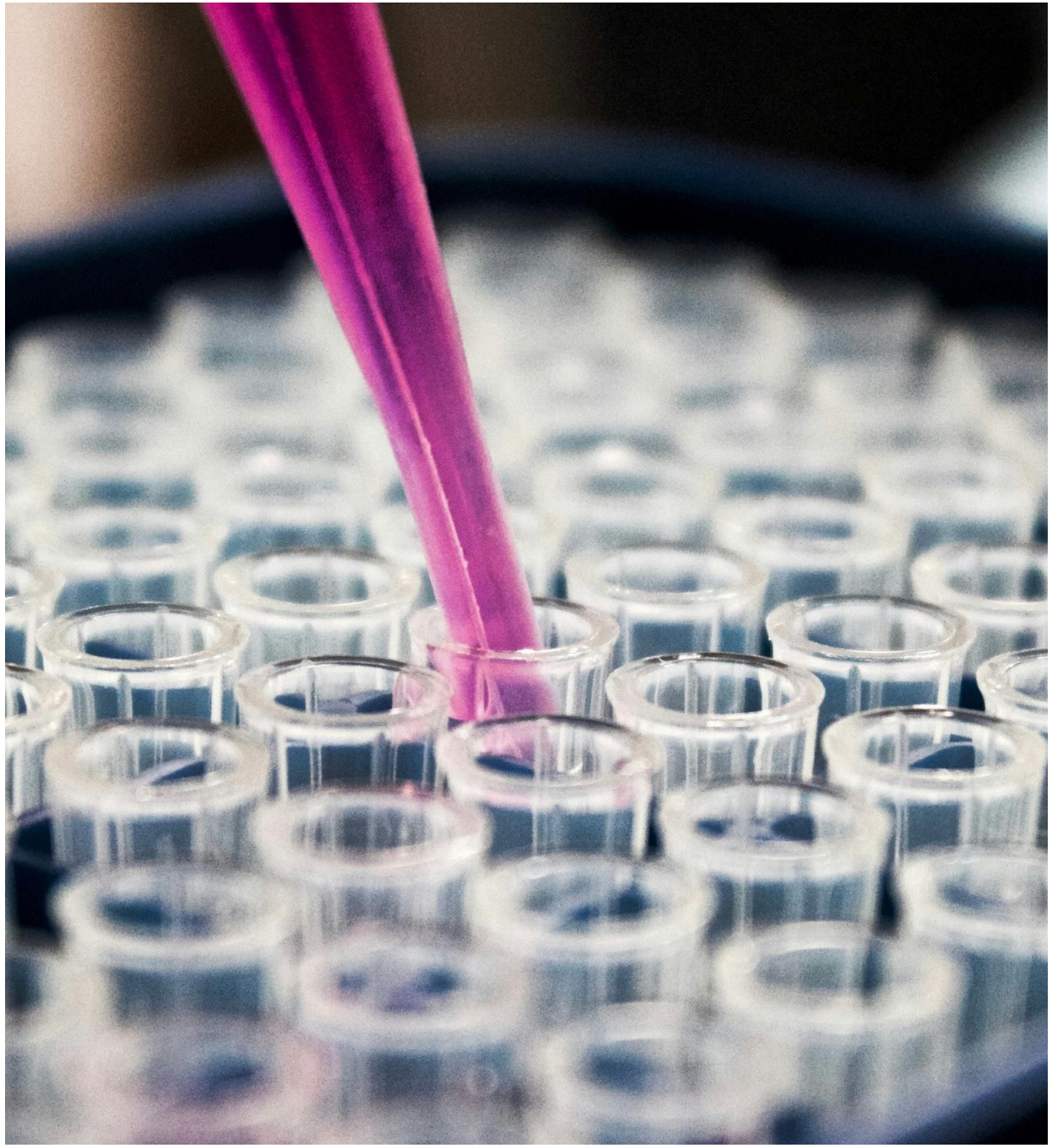
- RRP is the total number of days in the regulatory review period
- PGRRP is the number of days of the RRP which were on and before the date on which the patent issued ("post-grant")
- DD is the number of days of the RRP that the applicant did not act with due diligence
- TP is the testing phase period
- PGTP is the number of days of the TP which were on and before the date on which the patent issued
- Half days are ignored for purposes of the subtraction of ½(TP - PGTP).

- Then, consider 5-year and 14-year statutory limitations.

Miscellaneous Issues

SCOPE OF A PATENT TERM EXTENSION

- The scope of a patent term extension is limited by the “rights derived” provision of the PTE statute, 35 USC 156(b).
- This provision states that the “right derived” from the PTE award are limited to uses of the “product” that were approved before the original expiration of the patent under the same provision of law.
- Thus, a patent claiming a method of use of a drug for treatment of migraine and treatment of acne – based on FDA approval of a drug product for treating acne – cannot be enforced during the extended term of the patent against a competitor using the same drug for treatment of migraine.

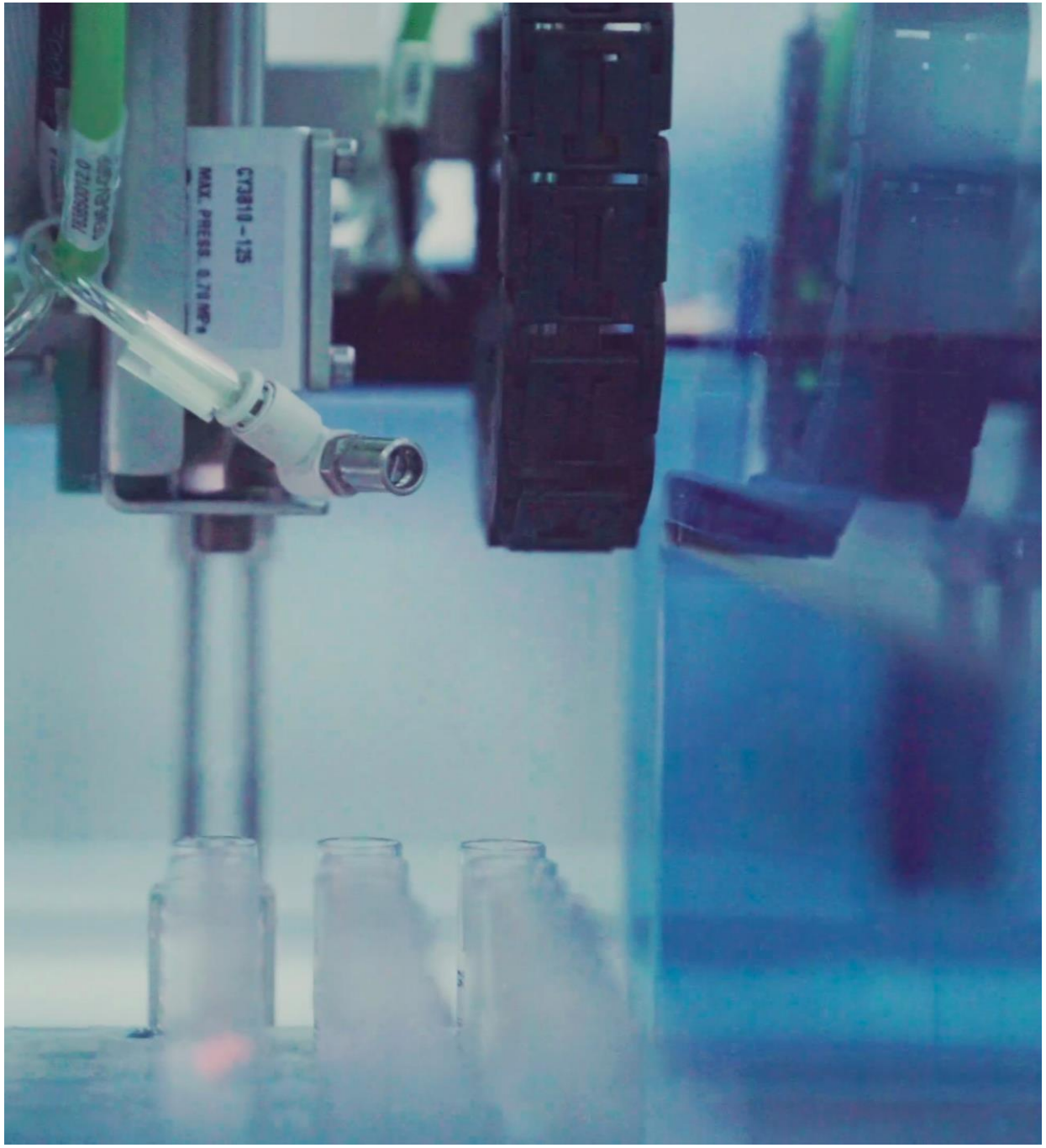


INTERIM EXTENSION: TWO TYPES

- Before FDA approval (35 USC 156(d)(5)):
  - If the regulatory review period is likely to extend beyond the original expiration date of the patent, the patent owner can submit an application for interim extension, during the period beginning 6 months before the patent term is due to expire and ending 15 days before the patent term is due to expire.
  - Available for extension up to one year, but subsequent interim extensions can be filed, for up to 5 years of interim extension.
- During review of PTE application (35 USC 156(e)(2)):
  - The USPTO will extend the term of a patent for up to one year, if would expire before final PTE determination is made.
  - Subsequent extensions up to 5 years.

MEDICAL DEVICES

- Where extension of a patent is sought based upon regulatory review under section 515 of the Federal Food Drug and Cosmetic Act of a medical device, the patent claims must include some physical structure of a device in order for the patent to be said to claim the product (or a method of using the product) thereby rendering the patent eligible for extension. *Angiotech Pharms. Inc. v. Lee*, 191 F. Supp. 3d 509 (E.D. Va. 2016).
- Only medical devices approved via PMAs under Section 515 of the FDCA are eligible for PTE.



TRENDS TO WATCH

- The USPTO appears to be taking steps to limit the number of PTE awards
  - No more multiple PTE's for same-day NDA or BLA approvals
  - Delays for products granted Accelerated Approval
  - Requests for information regarding "agency" relationship between NDA/BLA applicant and patent owner
  - Rolling NDA/BLA Submission: when is a marketing application "initially submitted"?

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