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Duty of Disclosure and Duty of Reasonable Inquiry

(USPTO Panel Discussion and *Belcher v. Hospira*)

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Overview

- Summarize recent issues regarding high drug prices.
- Discuss *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, (Fed. Circ. Sept. 1, 2021).
- Discuss USPTO panel discussion and presentation on Duty of Disclosure and Duty of Reasonable Inquiry.

Timeline Overview

- 2018, I-MAK "*Overpatented, Overpriced*" Report is published, updated Sept. 2022. TED talks and news interviews focusing on high drug prices and COVID-19 issues regarding access to vaccines.
- **July 9, 2021**, Biden's Executive Order on Promoting Competition in the American Economy (instructing the FDA to send a letter to the PTO).
- **September 15, 2021**, *Belcher Pharmaceuticals, LLC v. Hospira, Inc.*, (Fed. Circ.).
- **September 9, 2021**, Senators Leahy (D) and Tillis (R) sent a letter to PTO "requesting the PTO to take steps to reduce patent applicants' making inappropriate conflicting statements in submissions to the PTO and other federal agencies."
- September 10, 2021, FDA sent a letter to the PTO suggesting further engagement between the FDA and the PTO "to facilitate greater awareness of our complementary work and introduce efficiency in our respective workstreams."
- January 2022, Professor Adam Mossoff at the Hudson Institute published a Memo debunking the I-MAK data. Taking issue with "no access to I-MAK's underlying dataset" and spot checking some discrepancies.
- February 2022, Senator Tillis sent letter to FDA and PTO asking to investigate suspect I-MAK data. On April 1, 2022, Senator Tillis sends another letter to FDA and PTO reiterating the same request.

Timeline Overview Con't.

- June 8, 2022, six senators send a letter to the PTO about "patent thickets" and regarding high drug prices.
- July 6, 2022, PTO sends a letter back to the FDA including a list of ideas for lowering drug prices. PTO says we are doing a good and fair job, pharma patent filings have actually decreased. Also, maybe FDA should grant more "skinny labels." PTO agrees to share information with the FDA. Mentions possibly improving information disclosures.
- **July 29, 2022**, USPTO issued a Federal Register Notice: "Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board" (87 FR 45764-67). Appears to emphasize the "duty to perform an inquiry that is reasonable under the circumstances" and includes some strong language.
- October 4, 2022, the PTO issued a Request for Comments on a broad range of issues, including issues raised by I-MAK.
- **February 23, 2022**, PTO holds a virtual panel discussion on the duty of disclosure and duty of reasonable inquiry.

I-MAK

Tahir Amin

CO-FOUNDER
CO-EXECUTIVE DIRECTOR

Priti Krishtel

CO-FOUNDER
CO-EXECUTIVE DIRECTOR

Urgent Crisis

The drug pricing crisis has collided with a global pandemic and a long-overdue awakening with systemic racism. But this isn't only a moment of overlapping crises, it's a catalytic moment of reform.

Now is a CATALYTIC moment for reform

Drug Pricing Crisis + Global Pandemic + Racial Awakening

Biden Executive Order on Promoting Competition 7/9/2021

Americans are paying too much for prescription drugs and healthcare services — far more than the prices paid in other countries. Hospital consolidation has left many areas, particularly rural communities, with inadequate or more expensive healthcare options. And too often, patent and other laws have been misused to inhibit or delay — for years and even decades — competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs.

(vi) to help ensure that the patent system, while incentivizing innovation, does not also unjustifiably delay generic drug and biosimilar competition beyond that reasonably contemplated by applicable law, not later than 45 days after the date of this order, through the Commissioner of Food and Drugs, write a letter to the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office enumerating and describing any relevant concerns of the FDA;

Belcher Pharmaceuticals

Mr. Rubin

- Mr. Rubin, Belcher's Chief Science Officer (not an attorney or agent).
- Referred to as the "head of intellectual property."
- Involved in development and drafting of the new drug application (NDA) for epinephrine for FDA approval.
- Helped draft and prosecute patent 9,283,197 for epinephrine.
- He "project-managed everything" and "it all led to [him]."
- Served as liaison between the inventor, the patent attorney and the PTO.

Belcher's FDA Approval

- Belcher submitted a New Drug Application (NDA) for 1 mg/ml injectable l-epinephrine.
- Application discussed Sintetica's formulation developed in the 1930s which had a pH range of 2.2 to 4.0 (Swiss Company).
- Belcher explained they lowered the in-process pH from 2.8 to 3.3. (called "old") to a pH range of 2.4 to 2.6 (called "new").

Belcher's FDA Approval Con't.

- FDA requested additional information regarding racemization and stability validation.
- Belcher responded that racemization of l-epinephrine was a "well-known process" citing an article authored by Stepensky.
- Belcher stated the only difference between Stepensky was related to the in-process pH which was a "very minor change."
- FDA requested more evaluation from Belcher regarding the effect of the in-process pH range of 2.4 to 2.6.
- To avoid delay, Belcher reverted back to the pH range of 2.8 to 3.3 as shown in Sintetica and the FDA approved the NDA.

Belcher Patent U.S. 9,283,197

Two main claims at issue in the appeal:

6. An injectable liquid pharmaceutical formulation of l-epinephrine sterile solution;

said liquid pharmaceutical formulation having a pH between 2.8 and 3.3;

said injectable liquid pharmaceutical formulation compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine, and further including a tonicity agent;

said liquid pharmaceutical formulation including no more than about 6% d-epinephrine and no more than about 0.5% adrenalone at release, and no more than about 12% d-epinephrine and no more than about 0.5% adrenalone over a shelf-life of at least 12 months. (Emphasis added).

7. The said injectable liquid pharmaceutical formulation of claim 6 further having a concentration of 1 mg per mL l-epinephrine.

Belcher Patent U.S. 9,283,197 Con't.

- Patent '197 was allowed after one Office Action and an interview.
- Examiner rejected the claims as being obvious in view of a reference that had a pH range of 2.2 to 5.0.
- Belcher argued "criticality" for the claimed range of 2.8 to 3.3 and stated "was unexpectedly found to be critical by Applicant to reduce the racemization of l-epinephrine" and "achieves unexpected results."
- Examiner allowed the application "in view of Applicant's demonstration of criticality of a pH range between 2.8 and 3.3."
- The patent issued and the FDA listed the patent for Belcher's NDA.

Belcher v. Hospira (Fed. Cir. 2021)

- Belcher sued Hospira for infringement of their epinephrine patent ‘197. Hospira argued the patent was unenforceable.

- Belcher appeals the decision of the Delaware U.S. District court holding the patent unenforceable for inequitable conduct.

- The Federal Circuit affirms that Belcher’s Chief Science Officer, Mr. Rubin, engaged in inequitable conduct by withholding material information from the USPTO with requisite deceptive intent.

Belcher v. Hospira (Fed. Cir. 2021) Con't.

3 pieces of prior art improperly withheld by Mr. Rubin:

1) He knew of Sintetica's epinephrine formulations that had a pH range of 2.8 to 3.3. and Belcher's NDA described the range as "old."
2) Mr. Rubin admitted possessing an old epinephrine product by JHP having a pH in a range of 2.2. to 5.0.
3) The article by Stepensky showing the racemization relationship with pH is a well-known process.

Belcher v. Hospira (Fed. Cir. 2021) Con't.

Elements of inequitable conduct are:

1) "**materiality**" (only requires preponderance of the evidence), and
2) "**deceptive intent**" (clear and convincing standard).

The Federal Circuit cited *Therasense* and explained the prior art was "but-for material information" because disclosure of the prior art would have blocked issuance of the patent and held the most reasonable inference was that Mr. Rubin possessed the specific intent to deceive the PTO. The Federal Circuit affirmed the district court.

Federal Register Notice (87 FR 45764)

Duties of Disclosure and Reasonable Inquiry During Examination, Reexamination, and Reissue, and for Proceedings Before the Patent Trial and Appeal Board

- The Notice issued on July 29, 2022, and the Notice included some strong language.

- The Notice appeared to imply that anyone with a “duty to disclose” (37 CFR 1.56(b)) also has a “duty of reasonable inquiry.”

Federal Register Notice (87 FR 45764)

Some excerpts from the Notice:

- "Accordingly, each **party presenting** a paper to the USPTO, whether a practitioner or non-practitioner, **has a duty to perform an inquiry** that is reasonable under the circumstances. This reasonable inquiry may comprise reviewing documents that are submitted to or received from other Government agencies, including the FDA." (Emphasis added).

- "Similarly, each individual with a duty to disclose, or party with a duty of reasonable inquiry, **should review documents it receives from other Government agencies** to determine whether the information should be submitted to the USPTO." (Emphasis added).

- "[A]n Abbreviated New Drug Application (ANDA) **must contain a "paragraph IV certification"** that the patents submitted to the FDA by the brand-name drug's sponsor, listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book), and related to the drug are invalid, are unenforceable, or will not be infringed by the generic product." (Emphasis added).

- "If the content of the detailed statement, or other information that is part of the ANDA process, is deemed material to patentability in a pending USPTO matter, then **such information must be submitted to the USPTO** during the pendency of the matter, to meet the duties of candor and good faith and disclosure under 37 CFR 1.56, 1.555, 42.11(a) or (c), or 11.18(b)(2)." (Emphasis added).

USPTO Panel Discussion: Duty of Disclosure and Duty of Reasonable Inquiry

Moderator

Kimberly Braslow, AstraZeneca & Vice Chair, AIPLA Food and Drug Committee

Panelists

Robert A. Clarke, Director, Office of Patent Legal Administration

Ronald Jaicks, Senior Counsel for Disciplinary Investigations, Office of Enrollment and Discipline

Matthew Sked, Senior Legal Advisor, Office of Patent Legal Administration

Mary Till, Senior Legal Advisor, Office of Patent Legal Administration

USPTO Panel Discussion: Duty of Disclosure and Duty of Reasonable Inquiry Con't.

Duty of Candor and Good Faith (37 CFR 1.56(a))

- Each individual associated with the filing and prosecution of a patent application has a duty of **candor and good faith** in dealing with the Office.
- This duty includes the **duty to disclose** all information known to be **material** to patentability.

Who has the duty to disclose? (37 CFR 1.56(c))

- "Individuals associated with the filing or prosecution of a patent application."
- For example, the inventor(s), Attorney(s)/agent(s) who help with the application, every other person who is substantively involved with the application.

What information is "**material**" (37 CFR 1.56(b))

- It could be used by an examiner to reject a claim of the application; OR
- **It refutes a statement you made to the Office**.

USPTO Panel Discussion: Duty of Disclosure and Duty of Reasonable Inquiry Con't.

Duty of Disclosure – Tips (MPEP 2004)

- Make sure all Rule 1.56(c) individuals, especially foreign applicants and attorneys, understand their duty of disclosure.
- Submit information promptly.
- In close cases (e.g., a 50/50 situation), it is safest to submit the information for consideration by the examiner.
- Avoid large information disclosure submissions (e.g., eliminate clearly irrelevant and cumulative information).
- Materiality is not based on the source of or how you become aware of the information (MPEP 2001.06).
- Trade secret, proprietary, and/or protective order materials can be submitted (MPEP 724).
- 18 U.S.C. § 1001 applies, cannot lie to the government.

USPTO Panel Discussion: Duty of Disclosure and Duty of Reasonable Inquiry Con't.

37 C.F.R. § 11.18(b) Certifications and Duty of Reasonable Inquiry

- "Presenters" of papers to the Office make several certifications to the Office by operation of 37 C.F.R. § 11.18(b).
- "Presenting" means signing, filing, submitting, or advocating. See 37 C.F.R. § 11.18(b).

A presenter certifies that, to the best of his or her knowledge, information and belief, **formed after an inquiry reasonable under the circumstances**:

- Factual contentions have evidentiary support or, if specifically so identified, are likely to have evidentiary support after a reasonable opportunity for further investigation or discovery.
- Factual denials have evidentiary support, or if specifically so identified, are reasonably based on a lack of information or belief.
- Legal arguments are supported by existing law or a nonfrivolous argument for the extension, modification, or reversal of existing law or the establishment of new law.

See 37 C.F.R. § 11.18(b).

USPTO Panel Discussion: Duty of Disclosure and Duty of Reasonable Inquiry Con't.

What is "reasonable under the circumstances" in § 11.18(b)(2)?

- It depends on the particular facts of each case.

Disciplinary Decisions Providing Guidance

- *In re Tendler*, D2013-17 (Jan. 8, 2014), (did not inform about error in 131 declaration)
- *In re Anonymous*, D2014-05 (Apr. 1, 2014) (violation of duty to conduct reasonable inquiry)
- *In re Hicks*, D2013-11 (Sep. 10, 2013) (need to be truthful and candid)
- *In re Bollman*, D2010-40 (Oct. 19, 2011) (ways to submit confidential info)
- *In re Janka*, D2011-57 (Nov. 21, 2011) (ways to submit confidential info)
- *In re Hao*, D2021-14 (Apr. 2, 2022) (violation of duty to conduct reasonable inquiry)
- *In re Han*, D2022-23 (Jan. 6, 2023) (violation of duty to conduct reasonable inquiry)

Available at https://foiadocuments.uspto.gov/oed/

USPTO Panel Discussion: Duty of Disclosure and Duty of Reasonable Inquiry Con't.

Consequences for Violating 37 C.F.R. § 11.18(b) Certifications

Include but not necessarily limited to:

- Less probative value being given to the offending paper.
- Striking of the offending paper.
- Precluding a party from presenting or contesting an issue.
- Terminating the proceedings.
- Referring a presenter-practitioner's conduct to the Office of Enrollment and Discipline (OED) for action (e.g., investigation and institution of formal disciplinary action for alleged violation(s) of the USPTO Rules of Professional Conduct).

See 37 C.F.R. § 11.18(c) and (d).

USPTO Panel Discussion: Question and Answer Session

Question 1: what does the Notice clarify?

- Notice clarifies duties that currently exist, current duties already address the situation raised by the senators. The Notice was just a reminder, not meant to strong arm anyone.

Question 2: is Belcher an outlier?

- It is useful for practitioners (e.g., be aware of inconsistent statements), but it is a rare situation.

Question 3: what if you have different counsel for FDA and PTO?

- It depends on the specific facts. But you do not have to hunt for information. Also, do not create a wall between counsel before FDA and counsel before PTO. If you are aware of FDA proceedings, then it might be good to double check what was said before the FDA.

USPTO Panel Discussion: Question and Answer Session Con't.

Question 4: is it unreasonable to expect an attorney to make inquiries to different departments?

- Too hypothetical to give a clear answer, depends on the circumstances. The Notice gives some examples and makes it pretty clear.

Question 5: is Rule 56 duty of disclosure for people broader than duty of individuals regarding 11.18?

- Duty of inquiry is with the presenter, and the presenter may need to make additional inquiries to others, so 11.18 may have a broader reach but it owed by a single person. In other words, many people may owe a duty of disclosure but only the presenter of a paper to the Office owes the duty of reasonable inquiry. OED does not prosecute or investigate organizations, only the individual for duty of inquiry.

USPTO Panel Discussion: Question and Answer Session Con't.

Question 6: what is the difference between "duty of disclosure" (PTO) and "standard of inequitable conduct" (Fed Cir.)?

- Main difference is for "materiality." PTO has a lower standard defined by Rule 56(b) whether is raises a **prima facie case** regarding patentability. Federal Circuit has a higher "**but for**" standard, e.g., the PTO would not have issued the patent "but for" the withheld prior art (the standard was raised by SCOTUS). There is a delta.

Question 7: when can an examiner require more information?

- MPEP 704.10, Examiner must have a "reasonable basis," not a fishing expedition.

USPTO Panel Discussion: Question and Answer Session Con't.

Question 8: when might a submission to the FDA be relevant to the PTO?

- Look at the scope of the claimed invention and the timing of submissions to the FDA (e.g., a claimed manufacturing process). Note – once a patent has been granted, Rule 1.56(b) duty to disclose is over, unless there is a re-exam or other proceeding before the PTO.

Question 9: do clinical trials outside of the US need to be submitted to PTO (e.g., EMA)?

- If there is information that is material, then it needs to be provided to PTO. Watch out for what is provided in the **detailed statement** to the FDA if it is related to unpatentability of a claim that is currently pending at the PTO.

USPTO Panel Discussion: Question and Answer Session Con't.

Question 10: what if litigation council learns of something relevant to a continuation application handled by prosecution council?

- If it is material, it does not matter how you become aware of it, then disclose it. Secret information can be submitted under seal (MPEP 724). Or amend the claims to avoid the issue.

Question 11: why is a person from the Office of Enrollment and Discipline (OED) on the panel?

- No special role for OED. Federal Notice said no new rules for patent prosecution. Also, no new rules for the enforcement of ethical behavior. Simple mistakes are ok. At the end of the day, OED is doing nothing different, they just want to help and they have a hotline if anyone has questions for ethical obligations, e.g., "ask for a friend".

OED Hotline: 571-272-4097

Questions?

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