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The Honorable Bill Cassidy, M.D.
Chairman Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

The Honorable Bernie Sanders
Ranking Member Senate Committee on Health, Education, Labor and Pensions
428 Senate Dirksen Office Building
Washington, DC 20510

Dear Chairman Cassidy and Ranking Member Sanders:

As well-meaning as the proposal may be, the Medication Affordability and Patent Integrity Act ("MAPIA"), S. 2658, will lead to harassment and harm to the biopharmaceutical industry with no cognizable benefit in return. As such, this bill is unnecessary and will serve only weaken biopharmaceutical patents in a way not seen in any other technology.

The MAPIA bill in effect would require companies applying for patents on biopharmaceuticals to certify that the information they disclose to the FDA and PTO is not inconsistent or contradictory. The bill also creates a new basis on which to invalidate the patents at issue for intentional or even negligent failure to disclose the relevant information to either agency. Both provisions are meant to address concerns that biopharmaceutical companies are fraudulently obtaining patents to ward off generic and biosimilar market entry.

Biopharmaceutical companies already have duties of disclosure and candor to both the PTO and the FDA, however, as well as steep penalties for failing to meet those duties. The inequitable conduct defense to patent infringement already deters fraud during patent prosecution by invalidating the patent at issue. Likewise, the FDA already has the power to deny or revoke marketing approval for biopharmaceutical applications that are fraudulent, contain fraudulent data, or are submitted through fraud.

Critics nonetheless argue that these already existing measures are insufficient and call for more easily obtained penalties. They fault the inequitable conduct defense for requiring that any information withheld from the PTO during patent examination be not only material to patentability but also intentionally and not just negligently or recklessly withheld. Proving the latter can often be difficult, however, so critics call for a defense with less stringent requirements.

This ignores the history of the inequitable conduct defense and the Federal Circuit's very purposeful efforts to rein it in. Only a couple of decades ago, inequitable conduct claims had become so common that the Federal Circuit referred to them as an "absolute plague" that clogged the court system and led applicants to flood patent examiners with disclosures to avoid

later claims of withholding information. The Federal Circuit's decision in *Therasense, Inc. v. Becton, Dickinson, and Co.*, (Fed. Cir. 2011), therefore tightened the standard and limited the inequitable conduct defense to only where both materiality and specific intent to deceive are proven. Using MAPIA to provide a much less rigorous means of invalidating patents would re-open the floodgates of litigation abuse specifically for biopharmaceutical patents. This flies in the face of the Federal Circuit's concerted efforts to reduce such abuse.

More generally, however, critics argue that we need a way to facilitate greater communication between the PTO and the FDA – but this, too, already exists. Under 21 U.S.C. § 372(d), the Director of the PTO can ask the FDA "to furnish full and complete information with respect to such questions relating to drugs as the Director may submit concerning any patent application." The provision is designed to allow the PTO to avail itself of the FDA's expertise on the therapeutic effects of drugs, to the extent their relevant to the patentability of the invention at issue. Not surprisingly, the agencies have rarely used this provision because of the typically wide difference in time frames between applying for patent protection and applying for FDA approval – a problem that would plague MAPIA in the vast majority of cases as well.

Indeed, this problem with MAPIA is even greater than its potential for litigation abuse. Companies generally must apply for patent protection before applying for approval from the FDA to begin testing. This is in part because of the risk of losing patent eligibility but also in large part because clinical trials testing is extremely expensive as well as risky. Even for improvements on existing drug products or new indications for which those drugs can be used, testing is a prerequisite for FDA approval. No company wants to take such a huge step without the assurance of patent protection for its investment.

For this reason, any statements made to the FDA in applying for an Investigational New Drug approval or filing a New Drug Application will necessarily be subsequent to the patent application process. Patentability always is measured by the date a patent application is filed at the latest, however; statements later made in applying to the FDA therefore will have no bearing on patentability, as repeatedly held by both the Federal Circuit and the district courts. Later statements to the FDA mostly concern knowledge gained after invention, which is not relevant to patentability. In fact, courts have held that this is true even with regard to the inventors' statements about evidence that does predate the filing of a patent application. Although the evidence may be relevant to patentability, the inventors' understanding and perceptions of that evidence often changes because of what they learn during the invention process. Using the inventors' later statements would in this way be subject to hindsight bias and do not accurately reflect on the patentability of their inventions.

The obverse of course is true as well. A later statement to the FDA that appears inconsistent with an earlier statement to the PTO may merely reflect knowledge gained in the interim. As the court in Chiesi USA Inc. v. Aurobindo Pharma USA Inc., (D. N.J. 2022) noted, "statements made to the Patent Office [are] related to the legal standards for patentability (i.e., what was known at the time of invention . . . . ), while the statements made to the FDA [are] made after the invention and with knowledge of all of the development work that went into [a drug]." Id. at *30. It is therefore no surprise that in the very cases in which courts have allowed statements to the FDA to be used for issues of patentability, those statements or their contents all preceded patent application filing with the PTO.

More fundamentally, statements made to the PTO during the patent examination process and statements made to the FDA during the approval process are different in purpose and effect. Unlike the PTO, the FDA's remit is to examine not just the efficacy of a drug product as

used in humans but its safety as well. And because of the public health and safety concerns involved, the quantum of proof required varies between the PTO and the FDA as well. Whereas inventors are entitled to patents unless one or more exceptions is triggered, the FDA approves new drug products and new uses for those products only if its exacting standards are satisfied.

For example, "prophetic" statements of utility are acceptable for patentability purposes as long as phrased as such and credible. Operability need not be proven and certainly need not be proven to statistical significance. Indeed, actual reduction of inventions to practice to prove utility are helpful but never required for patentability. As noted in the Manual of Patent Examining Procedure (MPEP), for biopharmaceuticals this means that evidence of pharmacological or other biological activity is adequate to support an asserted therapeutic use "if there is a reasonable correlation between the activity in question and the asserted utility." Patent applicants do not need to prove either that this correlation actually exists, "nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted." Applications with the FDA, by contrast, not only must prove success in treating humans but also do so in a statistically significant manner. Thus, even if the FDA rejects for a drug to treat headaches, this does not mean that a company should not be able to get a patent for a drug based on such a claim.

Similarly, even if the FDA finds that a drug is too toxic for use in humans, that does not mean the drug is not patentable. Patent applicants need not show that an invention is safe. Rather, as the MPEP explains, the PTO "must confine its review of patent applications to the statutory requirements of the patent law. Other agencies of the government have been assigned the responsibility of ensuring conformance to standards established by statute for the advertisement, use, sale or distribution of drugs." (MPEP § 2107.3)

In sum: in the absence of any evidence that biopharmaceutical companies are rampantly making inconsistent representations to the PTO and the FDA in ways that undermine the integrity of the patent system, the MAPIA bill would serve only to further weaken biopharmaceutical patent rights. By subjecting them to frequent claims of invalidity based on failure to disclose, MAPIA would weaken protections that are vital for investment in the highly risky and difficult but incredibly important process of new biopharmaceutical research and development. Mechanisms already exist to discipline fraud on the patent office, and patent infringement defendants have more than adequate incentives to find any and all evidence of invalidity.

For all of these reasons, we respectfully urge the Committee to table S. 2658, the Medication Affordability and Patent Integrity Act.

Sincerely,

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cc:

Sen. Chuck Grassley, Chairman, Senate Committee on the Judiciary
Sen. Dick Durbin, Ranking Member, Senate Committee on the Judiciary
Sen. Thom Tillis, Chairman, Senate Judiciary Subcommittee on Intellectual Property
Sen. Adam Schiff, Ranking Member, Senate Judiciary Subcommittee on Intellectual Property
Sen. Maggie Hassan, Member, Senate Committee on Health, Education, Labor and Pensions
Sen. Josh Hawley, Member, Senate Committee on the Judiciary