January 31, 2023

The Honorable Kathy Vidal
Under Secretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: Request for Comments on USPTO Initiatives To Ensure the Robustness and Reliability of Patent Rights (PTO-P-2022-0025)

The Alliance of Community Health Plans (ACHP) appreciates the opportunity to comment on the U.S. Patent and Trademark Office's initiatives to ensure the robustness and reliability of patent rights. We continue to support USPTO's efforts to encourage innovation and ensure accessibility by ensuring patent rights are robust and reliable.

ACHP is the only national organization promoting the unique payer-provider aligned model in health care. ACHP member companies collaborate with their provider partners to deliver higher-quality coverage and care to tens of millions of Americans in 36 states and D.C. On behalf of our members, ACHP promotes reforms aimed at lowering drug costs by promoting transparency, competition and innovation. The U.S. Patent and Trademark Office plays a key role in maintaining the market dynamics responsible for incentivizing development of new cures but also in encouraging free and fair competition.

Unfortunately, the pendulum has swung too far in the direction of protecting brand drug monopolies. Blockbuster drugs are increasingly using the patent system to protect their monopolies long after they have recouped their investment and long after the drug can be considered novel. Bringing more competition to the prescription drug market will give consumers more choices and more control – resulting in lower prices and improved access. We commend the U.S. Patent and Trademark Office's commitment to ensuring a more balanced patent system and look forward to working with you to implement many of the practical solutions put forward in the agency's "request for comment".

ACHP believes the following reforms, considered in the request for comment are critical to addressing the high cost of drugs:

<u>Patent Thickets:</u>

Meaningful change must take aim at the root causes of high drug prices – and the growth and pervasiveness of patent thickets represents a clear target for such reforms. Patent thickets are built as a protective wall around a branded drug in order to block lower cost generic and biosimilar competition.

The patent thicket scheme relies on a maneuver known as "obvious-type double patenting" (OTDP), where duplicative or "non-patentably distinct" inventions are allowed, so long as they align each patent with a common expiry date (or terminal disclaimer). OTDP is only allowed in the U.S. In some cases, nearly 80% of a drug's patents are linked together by terminal disclaimers.

Challenging scores of patents, however, is not economically feasible for generic and biosimilar companies. Whether or not they are duplicative, competitors must invalidate every single patent to come to market. This scheme delays competitors and denies patients, health systems and the Medicare program significant savings.

We urge the USPTO to take steps to address this phenomenon by ending the use of terminal disclaimers to overcome OTDP rejections or by requiring the filing of a terminal disclaimer to include a binding admission that the claims are not patentably distinct from the previously granted claims to which they are obvious variations. This would ensure that duplicative patents, tied together by a terminal disclaimer, rise, and fall together when challenged in the court system.

FDA / USPTO coordination:

Greater coordination between the USPTO and FDA would improve patent quality and reduce tactics used to stagger follow-on patents in order to delay competition. FDA expertise would arm patent examiners with technical support when reviewing pharmaceutical inventions and researching special problems.

Importantly, information delivered to FDA for approval and USPTO for patent claims should be the same. Applicants should be required to certify that the statements they have made to USPTO are consistent with the statements they made to FDA. Implementing this reform would reduce the ability of branded drug companies to claim a new invention that was, in fact, obvious when the initial patent was filed.

Internal Process Improvements:

ACHP believes USPTO process changes would improve patent quality, including mitigating the examiner fatigue associated with repeated review of rejected claims. Indefinite review of rejected claims through requests for continued examination (RCEs) and the perpetual filing of continuation and divisional patent applications also has a chilling effect on competitors who may be weary of the uncertain exposure to infringement.

The “count system”, used to weigh examiners’ performance, incentivizes the granting of lower quality patents. We urge the USPTO to consider changing the incentive structure for examiners.

Written Description Rules:

Tightening written description rules to avoid unduly broad claims is key. The current practice allows branded pharmaceutical companies to patent features on which they have not performed clinical research. This limits the biosimilar makers’ ability to design around the originator and delays competition.

Quality Control Committee

ACHP supports the formation of a quality control committee to review all patents - not only continuation patents. The committee should act as a useful resource to examiners.

Fee Structure

With respect to USPTO's fee structure, we believe branded drug companies are unlikely to change their behavior, as revenue from a blockbuster drugs may reach tens of billions of dollars.

ACHP firmly believes that without major actions by USPTO and others, the brand pharmaceutical industry will continue to protect their monopolies, increase drugs costs, and jeopardize access for the patients who need them. ACHP looks forward to working with USPTO to foster competition and improve affordability for consumers seeking access to the treatments that can improve health outcomes and save lives.

Sincerely,

Dan Jones

Dan Jones

Senior Vice President, Federal Affairs

Alliance of Community Health Plans