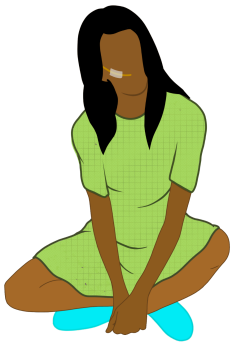
RE: Terminal Disclaimer Practice To Obviate Nonstatutory Double Patenting Proposed Rule (PTO-P-2024-0003)

Dear Director Vidal,



Generation Patient is a nonprofit created and led by young adults living with chronic and rare conditions, such as lupus, Crohn's disease, Lyme disease, rheumatoid arthritis, and more. Our organization creates a better future for young adult patients by building community and driving systems-level change. This includes driving policy changes that would ensure lower drug prices for our generation of patients. As part of our commitment to serving the true needs of our community, our organization does not accept private healthcare industry funding, including from pharmaceutical companies, insurers, or pharmaceutical benefit managers.

We eagerly await the day when the burden of high prescription costs is lifted from our shoulders. **We are reaching out to you at this critical juncture to support the proposed rule.** This step is crucial to ensure timely access to biosimilars and generics and catalyze significant improvements in the prescription drug landscape.

By using terminal disclaimers to respond to *obviousness-type double patenting*, pharmaceutical companies can build large patent thickets around existing high-cost prescription drugs. These additional patents are often not meaningful to us as patients and wrongly extend market exclusivity for drugs with no additional clinical benefits. A case example of this is Humira, which many in our community rely on for multiple autoimmune conditions. Such thickets act to keep prices prohibitively high, resulting in negative health outcomes for the most vulnerable. Even more astounding is that drug companies will accumulate many of these patents after FDA approval.

To help address these patent thickets, the USPTO has proposed linking the enforceability of terminally disclaimed patents with their corresponding 'parent' patents. This measure aims to reduce the incentive to accumulate numerous duplicative patents on life-saving medications. Additionally, this solution is surgical. The proposed rule targets the least innovative patents while leaving truly groundbreaking patents untouched. The proposed policy maintains the ability of brand-name drug manufacturers to obtain such patents while preventing undue delays in appropriate competitive market entry.

As we see the campaigns from brand-name pharmaceutical trade organizations attacking efforts to reform the patent system benefitting patients like us, we recognize even more how crucial it is for regulators to hear from public interest and community groups. We do not represent private interests, we represent the lived experiences of navigating chronic illness in young adulthood. This rule impacts our ability to afford medicines as we enter adulthood. We believe in balancing

rewarding innovation with ensuring fair and timely access to biosimilars and generics. This rule is an exciting step forward.

Sincerely,

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