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March 14, 2023

The Honorable Maryellen Noreika  
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*Via email and FedEx*

**Re: *United States v. Gilead*, No. 1:19-cv-02103 (D. Del.)**

Dear Judge Noreika,

I write on behalf of my clients, the Public Interest Patent Law Institute (“PIPLI”) and PrEP4All, to draw your attention to what appear to be improperly sealed court records in the case *United States v. Gilead*, No. 1:19-cv-02103. We ask, respectfully, that you take certain steps to remedy these improprieties.

Given the importance of this case, my clients have a strong interest in ensuring that the public’s right of access to judicial records is protected. Therefore, we respectfully request your prompt attention to this matter.

*A. PIPLI and PrEP4All*

PIPLI is a nonprofit public interest organization that works to improve the patent system’s ability to promote innovation for the benefit of all.<sup>1</sup> In service of its mission, PIPLI gathers and disseminates information about developments in patent law and policy, submits FOIA requests, policy comments, and amicus briefs on patent-related issues, and advocates for broader participation in the patent system.<sup>2</sup> PIPLI also seeks access to improperly sealed court records in patent cases.<sup>3</sup>

PrEP4All is a nonprofit public interest organization of community members, healthcare professionals, lawyers, and academics all dedicated to increasing access to lifesaving HIV

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<sup>1</sup> See generally Public Interest Patent Law Institute, About, <https://www.piplius.org/about> (last visited March 8, 2023).

<sup>2</sup> *Id.*

<sup>3</sup> See, e.g., Mot. of the Electronic Frontier Foundation and Public Interest Patent Law Institute to Intervene and to Unseal Ct. Rs., *Uniloc 2017, LLC v. Google, LLC*, No. 2:18-cv-00499 (E.D. Tex. Apr. 25, 2022).

medication.<sup>4</sup> In service of its mission, PrEP4All gathers and disseminates information about developments in HIV prevention and treatment policies and organizes public events.<sup>5</sup> PrEP4All's interest in this case and its underlying subject matter was recognized by the U.S. government itself, which cited PrEP4All in its complaint.<sup>6</sup>

### *B. Posture*

On November 6, 2019, the United States government filed its complaint against Gilead Sciences, Inc. and Gilead Sciences Ireland UC (together, "Gilead"), alleging that Gilead infringes upon certain government-owned patents when it markets and sells Truvada and Descovy.<sup>7</sup> The asserted patents cover HIV prophylaxis ("HIV PrEP," or simply "PrEP") and were obtained by the Centers for Disease Control and Prevention ("CDC").<sup>8</sup> A 10-day jury trial is scheduled to begin on May 1, 2023.<sup>9</sup>

Since its inception in 2019, the *United States v. Gilead* case has attracted widespread attention from civil society, academia, news media, and the broader public.<sup>10</sup>

PrEP4All and PIPLI have followed the *United States v. Gilead* case with great interest. In January 2022, PrEP4All organized a letter of HIV/AIDS service providers and advocacy groups to the Department of Health & Human Services ("HHS") and Department of Justice ("DOJ"), seeking an update on the status of the litigation.<sup>11</sup> As the letter noted, "[t]he lawsuit brought by DOJ and HHS—*United States v. Gilead*—was a historic move lauded by many in the HIV and access to medicines movements."<sup>12</sup> The letter asked HHS and DOJ to provide, inter alia, "relevant updates to the community regarding the status of *United States v. Gilead*."<sup>13</sup> HHS and

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<sup>4</sup> See generally PrEP4All, Our Story, <https://www.prep4all.org/our-story> (last visited March 8, 2023).

<sup>5</sup> See generally PrEP4All, Mission, <https://www.prep4all.org/mission> (last visited March 8, 2023).

<sup>6</sup> Complaint at 50-51, *United States v. Gilead*, No. 1:19-cv-02103 (D. Del. Nov. 06, 2019).

<sup>7</sup> D.I. 1. References to "D.I." refer to the case at hand, No. 1:19-cv-02103, unless otherwise noted.

<sup>8</sup> D.I. 1 at 2.

<sup>9</sup> D.I. 27.

<sup>10</sup> See, e.g., Christopher Rowland, *Trump Administration Sues Drugmaker Gilead Sciences Over Patent on Truvada for HIV Prevention*, The Washington Post (Nov. 7, 2019); Tim Fitzsimons, *U.S. Sues Gilead, Claiming it Owns HIV PrEP Patent*, NBC News (Nov. 7, 2019); Jon Cohen, *Untangling the Trump Administration's Lawsuit Over an HIV Prevention Drug*, Science (Nov. 8, 2019); Christopher Morten & Amy Kapczynski, *United States v. Gilead: Can a Lawsuit Yield Better Access to PrEP?*, Health Affairs (Nov 18, 2019); Lawrence O. Gostin & Arti K. Rai, *Expanding Access and Reducing Prices for Drugs to Prevent HIV*, 323 JAMA 821 (Mar. 3, 2020), doi:10.1001/jama.2020.0442; Adam Lidgett, *Gilead Wants US to Face Defenses Before HIV Patent Trial*, Law360 (Jan. 24, 2023).

<sup>11</sup> *United States v. Gilead: Two Year Anniversary Letter* (Jan 20, 2022), <https://www.prep4all.org/news/us-v-gilead-anniversary>.

<sup>12</sup> *Id.*

<sup>13</sup> *Id.*

DOJ did not respond to the letter. To our knowledge, HHS and DOJ have not otherwise updated the HIV/AIDS community or the broader public on the case.

In late 2022, the parties filed motions for summary judgment.<sup>14</sup> PrEP4All and PIPLI hoped these motions would provide them, and the broader public, with long-awaited substantive updates on the major issues in dispute in the case. Gilead filed its motion for summary judgment on October 13, 2022.<sup>15</sup> The United States filed its own motion for partial summary judgment on the same day.<sup>16</sup> These motions remain pending as of writing.

However, PrEP4All, PIPLI, and the broader public cannot fully understand, or even identify, all the issues in dispute at summary judgment because public versions of the parties' motion papers have been entirely sealed or heavily redacted. For example, the parties' opposition and reply briefs and many of their declarations and other evidence, are sealed, in whole or in part.<sup>17</sup> The extent to which these dispositive motion papers are sealed is especially concerning. In addition, other court records separate from the parties' summary judgment papers also appear to be improperly sealed.<sup>18</sup>

Moreover, neither my clients nor the public know *why* any of the court records in this case were sealed. It appears that neither the United States nor Gilead has ever filed a motion to seal arguing that secrecy is necessary for any of these sealed filings. Accordingly, the Court has never issued an opinion articulating the grounds on which they were sealed. As we explain in more detail below—*infra* § E—it therefore appears that the parties have sealed these materials improperly, in violation of the public's right to access to court records in this district.

*C. The Constitution, the common law, and Third Circuit precedent guarantee a right of public access to court records.*

Under the Constitution and the common law, the public has a presumptive right of access to judicial proceedings and judicial records. *Nixon v. Warner Communications*, 435 U.S. 589, 597 (1978). This right of public access ensures that courts are publicly accountable and thus protects the public's faith in the court system. While the right of public access is not absolute, the Third Circuit upholds a "strong" presumption to the right of public access. *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994).

The right of access to court records serves important functions in a democratic society. It allows the public to observe the administration of publicly funded courts, enhances the fairness

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<sup>14</sup> D.I. 344; D.I. 350.

<sup>15</sup> D.I. 344.

<sup>16</sup> D.I. 350.

<sup>17</sup> *See, e.g.*, D.I. 45-350; D.I. 364-367; D.I. 375-381; D.I. 393-394; D.I. 397.

<sup>18</sup> D.I. 316-317; D.I. 385

of court proceedings, and maintains the public trust on which the judiciary's institutional legitimacy depends.

*D. Binding Third Circuit precedent establishes a high barrier to seal in contravention of the right of access.*

The Third Circuit recognizes that the public's right to access attaches to many court records, including (but not limited to) "pretrial motions of a nondiscovery nature, whether preliminary or dispositive, and the material filed in connection therewith." *Leucadia Inc. v. Applied Extrusion Techs., Inc.*, 998 F.2d 157, 164 (3d Cir. 1993). The Third Circuit recently held explicitly that summary judgment motions and their associated exhibits are subject to a strong presumption of accessibility to the public. *In re Avandia Mktg., Sales Practices and Products Liab. Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). As Chief Judge Connolly of the District of Delaware has stated, "[i]t is very, very hard to keep something under seal in the Third Circuit, and it's the Third Circuit that governs." Transcript of Evidentiary Hearing at 51:10-12, *Lamplight Licensing LLC v. Ingram Micro, Inc.*, No. 1:22-cv-01017 (D. Del. Nov. 4, 2022). Chief Judge Connolly has also stated that "[t]he District Court is not a Star Chamber." *Genentech, Inc. v. Amgen Inc.*, C.A. No. 17-1407-CFC, 2020 U.S. Dist. LEXIS 54775, at 11 (D. Del. Mar. 30, 2020).

Throughout the Third Circuit, the party seeking to seal any judicial record subject to the public's right of access must satisfy "a heavy burden." *Miller* at 551. "The public's right of access is not absolute; but it is strongly presumed, and it can be overcome only if a party demonstrates that public disclosure of a filing will result in 'a clearly defined and serious injury.'" Memorandum Order at 4, *In re: Salesforce, Inc.*, No. 1:23-mc-00027-CFC (D. Del. Feb. 24, 2023) (quoting *Avandia* at 672). To overcome the presumption of the right of public access, the party urging secrecy must persuasively demonstrate specific, concrete, and particularized harm. *Avandia* at 676. The *Avandia* court emphasized that "specificity is essential" in "delineating the injury to be prevented" and that "broad allegations of harm, bereft of specific examples or articulated reasoning are insufficient." *Id.* at 677-78 (quoting *LEAP Sys., Inc. v. MoneyTrax, Inc.*, 638 F.3d 216, 221-22 (3d Cir. 2011)). For example, litigants "merely stat[ing] that the redacted information is 'competitively sensitive' or, in one case, 'privileged'..." "...fail to overcome the presumption of access." Order Den. Pls.' Mot. to Retain Under Seal at 2, *Siemens v. Geisenberger*, No. 1:19-cv-02284-MN (D. Del. Oct. 31, 2022). To demonstrate that harm with the requisite specificity and thereby establish an entitlement to secrecy, the appropriate course of action for the party urging secrecy is to submit an appropriate motion to seal. *See Avandia* at 676.

To ensure that proper weight is given to "the public's strong interest in the openness of judicial records," this Court must engage in a "document-by-document review" of records one or more parties seek to seal, in whole or in part. *Id.* at 677-78. When granting a sealing order, this Court "should articulate 'the compelling[,] countervailing interests to be protected,' make "specific findings on the record concerning the effects of disclosure, and provide[] an opportunity for interested third parties to be heard." *Id.* (quoting *In re Cendant Corp.*, 260 F.3d 183, 194 (3d Cir. 2001)).

*E. The parties have not satisfied the requirements and procedures necessary to overcome the right of access.*

As stated above, Gilead and the United States have filed many records, including summary judgment papers, under seal, without a single motion to seal. As a result, the Court has not yet had an opportunity to issue an opinion articulating the grounds on which the records were sealed. This unexplained sealing violates the public's right of access guaranteed by the common law and First Amendment and enshrined in Third Circuit precedents.

For example, we respectfully direct your attention to the redacted version of Gilead's opening brief in support of summary judgment.<sup>19</sup> The public version of this brief is heavily redacted, including practically an entire page of text, as shown below:<sup>20</sup>

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<sup>19</sup> D.I. 355.

<sup>20</sup> D.I. 355.

GSIUC is a wholly owned subsidiary of Gilead based in Ireland. [REDACTED]

[REDACTED]

Given the extent of these redactions, combined with the parties' failure to submit sealing motions, PIPLI and PrEP4All cannot say with any certainty what type of information was sealed or why. Prior to filing its heavily redacted motion, Gilead alleged no harm that would flow from disclosure of this information, let alone the "specific, concrete, and particularized harm" the law requires it to prove. Instead, Gilead simply assumed a right to secrecy and filed its motion for summary judgment with heavy redactions.<sup>21</sup>

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<sup>21</sup> D.I. 355.

In permitting Gilead to place large swathes of this court record under seal, this Court did not engage in the “document-by-document review” required by binding Third Circuit precedent. Nowhere in the docket is an articulation of Gilead’s alleged interests in secrecy nor any specific findings on their sufficiency in comparison to the public’s interest in understanding the arguments and issues before this Court at summary judgment.

*E. Requested Action*

Gilead’s summary judgment motion<sup>22</sup> is merely one example of the improperly broad and unexplained extent of redaction in this docket. As the presiding judge, you are the public interest’s principal champion. You have the ability and responsibility to address apparent sealing violations and vindicate the public’s right of access.

We respectfully request the Court take the following actions:

- i. Require the parties to justify the current extent of sealing by requiring them to file motions to seal for the summary judgment and other papers they have already filed under seal. If the Court determines the parties’ motions to seal do not satisfy the Third Circuit’s requirements for sealing, in whole or part, the sealing requests should be denied, and the filings (or the appropriate portions thereof) should be made available on the public docket (via PACER). If the Court decides that the parties’ sealing motions overcome the presumption of public access to any court record, in whole or part, we respectfully request that the Court articulate the reasons for that decision in a public order.
- ii. Going forward, require the parties to file motions to seal any additional filings that they seek to seal, in whole or in part.
- iii. Ensure that the public is provided with robust access to the trial itself, including its exhibits and testimony, as is required by the common law and the First Amendment.

\* \* \*

The Constitution and common law grant the public presumptive rights of access to judicial filings and proceedings. Third Circuit precedent clearly establishes the process parties must follow and the heavy burden they must satisfy to overcome the presumption of public access.

In this case, Gilead and the DOJ appear to have disregarded the public’s rights of access as well as Third Circuit procedure by filing sealed and redacted versions of their filings without providing any justification for such sealing.

You have the authority to correct these violations and protect the public’s right of access by requiring the parties to provide justification for such sealing pursuant to Third Circuit law.

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<sup>22</sup> D.I. 355.

PIPLI and PrEP4All respectfully request the Court's prompt attention to this matter. We will continue to watch this case closely.

Respectfully submitted,<sup>23</sup>

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<sup>23</sup> Counsel expresses his gratitude to Columbia Law student April Yu for researching and drafting portions of this letter. Counsel also thanks Columbia Law alumna Kate Kobriger for her many contributions to the letter.

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