

FROM: Eric Sawyer, Petitioner, March-in Request related to Prostate Cancer Drug Xtandi
TO: The Honorable Xavier Becerra, Secretary, the Department of Health and Human Services,
The Honorable Lawrence Tabak, Acting Director, the National Institutes of Health
RE: Procedural Fairness and Transparency in the Review of Xtandi March-In Petition
DATE: February 4, 2022

Dear Secretary Becerra and Acting Director Tabak:

I am writing in my capacity as the attorney for Eric Sawyer, a petitioner in the request asking the Department of Health and Human Services (HHS) to march in and exercise other rights in the patents on the prostate cancer drug Xtandi. I write to raise questions and concerns about the procedures being followed by the National Institutes of Health (NIH) in adjudicating the petition. The process as indicated by the NIH raises serious red flags that the agency intends to arrive at a decision in an unnecessarily hasty time frame, after a one-sided process that lacks transparency and fairness. The outcome of the NIH's decision will have reverberations for prostate cancer patients, consumers, and taxpayers for decades to come. The NIH is unlikely to arrive at an appropriate decision on the merits if the procedures it utilizes to arrive at its decision are unfair and opaque.

I therefore also write to urge the NIH to reverse course, and to implement transparent and fair procedures outlined in this memorandum, such as convening a public hearing, creating a briefing schedule, and/or establishing a public docket for receiving comments.

These procedures should be implemented now, as the NIH determines whether it has received information that might warrant the initiation of march-in proceedings—an issue on which all stakeholders are entitled to a full and fair right to be heard, because it determines whether the petition terminates or moves forward.

Background

On January 10, 2022, NIH Acting Deputy Director Tara Schwetz sent petitioners Robert Sachs and Clare Love an email stating that the petition, which was directed at HHS, will be reviewed by the NIH Office of the Director within approximately 30 days, and that “[t]he issue of whether a hearing should be held would only arise later, subsequent to a decision by the agency to initiate a march in proceeding, consistent with the procedures set forth in 37 CFR 401.6.”

Discussion

In this memorandum, I will address the following points:

1. The NIH is authorized to convene a public hearing regarding the initial determination as to whether to move forward with the march-in request.
2. The procedures that the NIH is proposing are opaque, hasty, and unfair.

3. The procedures that Mr. Sawyer is requesting herein—a public hearing, public docket, and briefing schedule—would make the process transparent and fair, and would ensure greater public confidence in the outcome.
4. The NIH has adequate time to grant the procedures requested by Mr. Sawyer.

1. The NIH is authorized to convene a public hearing regarding the initial determination as to whether to move forward with the march-in request.

Dr. Schwetz's email appears to suggest, inaccurately, that the NIH cannot grant a hearing now as to the initial determination of whether to move forward with the petition, because the regulations at 37 C.F.R. § 401.6 state that a hearing arises later, only if the NIH decides to move forward. This does not have to be the case. Both the regulations governing march-in rights and historic practice are consistent with convening a hearing now, as to the initial question of whether to initiate march-in proceedings.

The regulations establish only *minimum* safeguards that agencies must follow when responding to march-in petitions, but give agencies the flexibility to issue additional procedures, as long as the additional procedures are not inconsistent. *See id.* § (l). Such supplemental procedures permitted by the regulations include a hearing, public docket, and briefing schedule, because none of these procedures would deprive the respondents of certain guaranteed rights. They would merely give petitioners and other stakeholders equal treatment with respondents and create a more balanced playing field between the parties.

This interpretation of the regulations as permitting a hearing at this early stage is supported by historic practice. In 2004, the NIH convened a public hearing on the petition requesting the agency to march in on patents related to the HIV drug Norvir. The hearing was focused on the initial inquiry of whether or not the petition presented information that warranted initiating march-in proceedings. As Dr. Mark Rohrbaugh, Senior Technology Transfer Advisor with the NIH, stated in his introductory comments:

The purpose of this public meeting is to give us an opportunity to listen to comments from representatives of constituencies and to hear various points of view. These comments and viewpoints then will be considered by the NIH in making the decision of whether we have received information that might warrant the exercise of march-in rights. The NIH will make that initial determination and, if necessary, will initiate any formal march-in proceeding as required under the regulations.¹

The regulations on march-in proceedings were materially the same in 2004 as they are today, yet the NIH determined then that it would be appropriate and useful to convene a hearing as to the initial question of whether to exercise march-in rights. The same is true today.

¹ *See*, Nat'l Insts. of Health, *NIH Public Meeting on Norvir/Ritonavir March-in Request* (May 25, 2004) <https://www.ott.nih.gov/sites/default/files/documents/2004NorvirMtg/2004NorvirMtg.pdf>.

There is also historic support for a briefing schedule and oral argument. In the late 1990s to early 2000s, the Department of Energy (DOE) adjudicated a petition to march in on patents related to fluorescent in situ hybridization (FISH) tests for breast cancer. As to the initial inquiry of whether to initiate march-in proceedings, the DOE devised and implemented detailed procedures, including a briefing process with deadlines for filing a reply, rebuttal, and surreply, and oral argument. The DOE also convened a panel of decision makers to make the determination following the oral argument.

These are just two examples of approaches taken by agencies when reviewing earlier march-in petitions that ensured greater transparency and fairness than the procedures that the NIH is needlessly insisting on now. The examples also refute the argument that a hearing would only arise later, after the NIH has determined whether to initiate proceedings.

2. The procedures that the NIH is utilizing are neither fair nor transparent.

Fairness requires equal treatment between the petitioners and respondents, and the public interest would be served by transparent procedures. As it stands, the NIH is not affording petitioners and respondents the same procedural protections. The NIH's process is creating a glaring, unfair disparity between the stakeholders.

The regulations state that, at this stage, the NIH must accept written and oral comments from respondents. Respondents are thus able to review and respond to the petition, but petitioners can neither review, nor can they respond to, the oral and written comments that are being submitted by respondents. If the comments are oral, there will be no record of them. If they are written, it is highly unlikely that petitioners could access them (through Freedom of Information Act (FOIA) requests) and respond to their arguments before a decision is made. The NIH has emphasized how an influx of new FOIA requests has slowed down its response time.

It is also likely that the NIH is having *ex parte* communications with lobbyists about the petition. I have reviewed a number of emails obtained under a previous FOIA request between NIH officials and individual lobbyists for university and pharmaceutical rights holders who routinely correspond with NIH technology transfer officials and have a professional interest in opposing the enforcement Bayh-Dole Act legal safeguards such as march-in rights and the royalty-free license. This is inconsistent with rule of law and harmful to the public interest in access to taxpayer-funded inventions on reasonable terms. *See* 35 U.S.C. § 200.

The emails demonstrate that the NIH gives those individuals assistance, information, and other inroads that it does not give members of the public, and that the NIH collaborates with those individuals about the weakening of public interest safeguards in subject inventions under the Bayh-Dole Act. There is thus a possibility or even likelihood that the NIH is currently communicating with these individuals, in secret, about the petition.

If the NIH were to render a hasty decision after having secretive, backdoor discussions with respondents or with those who have professional interests in weakening Bayh-Dole Act

safeguards, that would be akin to a biased judge having *ex parte* communications with one party to a pending case—an outcome that no one could assert was procedurally fair.

3. The procedures requested in this letter would promote fairness, transparency, and public confidence in the NIH's decision making process.

There are several ways that the NIH can create a more just and transparent process and address the problems identified in this letter.

First, as to the issue of *ex parte* written communications, we believe that the NIH can create a public docket, as does the United States Food and Drug Administration when it receives a citizens' petition, and publicly post all comments to the docket. In this manner, members of the public, petitioners, patients, and respondents could all respond to any information or argument posted by any other group and individual. If respondents were aware that their comments might receive public scrutiny, they are more likely to be truthful. Furthermore the general public, as consumers and taxpayers, are going to feel the impact of the NIH's decision, one way or another, and therefore should have a right to scrutinize respondents' statements.

A public docket is appropriate in this context, and the submissions will be sharper if they can respond to what is privately being said by the respondents. There is a mix of factual and legal issues needing resolution, all of which would benefit from a transparent public debate.

Legally, the NIH historically has applied a distorted legal standard when assessing march-in petitions grounded in failure to achieve "practical application," stating that the standard is met based on an invention's availability to the public, with no mention of the requirement that the invention be available "on reasonable terms," which appears in both the Bayh-Dole Act and implementing regulations. 35 U.S.C. § 201(f); 37 C.F.R. § 401.2 (e). The Biden administration has rejected the National Institute of Standard and Technology's attempt to narrow the practical application standard through an illegal regulatory amendment. The Xtandi petition thus presents an important opportunity to reexamine the NIH's erroneous previous legal position, which is best done through a transparent briefing process.

As a factual matter, the proverbial elephant in the room is how Astellas Pharma justifies the exorbitant cost of Xtandi and the price discrimination against U.S. residents, whose taxpayers' dollars helped fund the drug's development. This is an issue that will likely involve disputed questions of fact that are better explored through a transparent briefing process. Astellas has a direct financial interest in presenting a slanted, and possibly inaccurate, picture of the impact of its drug pricing decisions on U.S. patients. To put it bluntly, Astellas will lose profits if the petition succeeds, though it has earned \$20 billion in sales from Xtandi. It is only fair and reasonable that the public has an opportunity to meaningfully scrutinize its claims.

U.S. prostate cancer patients have a unique perspective and information that differs from that presented by Astellas. The NIH has historically treated as relevant issues such as patient assistance programs and co-pays, and cited them as a basis for denying petitions. Setting aside

whether those issues are dispositive, it is important to note that Astellas is not the sole source of information on that topic, nor is it the most credible one.

Previously, Astellas has made claims to the NIH about its patient assistance programs. Mr. Sawyer has no way of knowing what, if anything, Astellas is saying about such programs today, but we would like these statements to be on the record and to have the opportunity to evaluate and rebut misleading or inaccurate assertions, particularly given the far different experiences regarding copayments of which he is aware.

These differences should be aired out in a public manner. A party is more likely to be truthful when its submission is subjected to public scrutiny and possible rebuttal. Moreover, if the NIH does not create a public docket, patient submissions to the NIH will not be aired publicly, and the public would benefit from hearing from the patient perspective.

Alternatively, or in addition to a public docket, the NIH could issue a briefing schedule establishing a deadline for petitioners to respond to any written response to the petition, and for respondents to submit a surreply to the rebuttal, as did DOE with the FISH march-in petition. A briefing schedule, too, would sharpen the arguments and crystalize ideas.

Third, the NIH could convene a hearing, which would be helpful in ensuring a fair and transparent process as to the submission of oral comments. Without a hearing, the respondents could simply call the NIH and offer their comments orally, with no record of the communications. Petitioners and members of the public cannot respond to a communication for which there is no record, nor can the NIH ensure transparency or fairness as to the contact, if there is no record of it. Further, petitioners and other constituents have not been afforded the same opportunity to give their oral comments. But even if the NIH were to allow petitioners and other members of the public to offer their oral comments, it would be disorderly and illogical to have every interested party give their oral comments at different times, behind closed doors, without a record.

In addition, there are some matters that are best communicated orally, such as the personal impact of excessive prescription drug prices on patients. Petitioners appreciate the fact that the NIH has accepted their written submissions, but text does not communicate emotional impact to the same extent as live testimony. For these reasons, a public hearing should be convened so that all oral comments are offered in one transparent forum.

4. The NIH has adequate time to grant a hearing and provide other procedural protections.

Dr. Schwetz's email also indicated that the NIH will complete its review within approximately a month of January 10, 2022. Again, such an abbreviated process is contrary to—not consistent with—federal regulations governing march-in rights, so they offer no cover for the NIH's decision to insist on such an unnecessarily hasty process.

The regulations governing march-in proceedings state, in pertinent part:

(b) Whenever an agency receives information that it believes might warrant the exercise of march-in rights, before initiating any march-in proceeding, it shall notify the contractor in writing of the information and request informal written or oral comments from the contractor as well as information relevant to the matter. In the absence of any comments from the contractor within 30 days, the agency may, at its discretion, proceed with the procedures below. If a comment is received within 30 days, or later if the agency has not initiated the procedures below, then the agency shall, within 60 days after it receives the comment, either initiate the procedures below or notify the contractor, in writing, that it will not pursue march-in rights on the basis of the available information.

37 C.F.R. § 401.6 (b). There are several important facets to this provision, all of which demonstrate that a 30-day review period is unnecessarily hasty. First, the agency must give a contractor (or assignee or licensee) a minimum of 30 days to respond, starting from the date that the agency sent notice of the petition to the respondent. If the contractor responds within 30 days, the agency has an additional 60 days to decide whether to move forward. This means that *if* the University of California, Los Angeles, Astellas Pharma, or Pfizer responds, the NIH potentially has 90 days from the day that it sent its notice of the march-in petition, to convene a hearing, create a public docket, and afford other protections. If, on the other hand, the NIH does not receive a response within the specified time frame, the NIH may proceed at its discretion—at any time.

In any event, it is clear that a 30-day decisionmaking timetable is the shortest conceivable time table provided by the regulations, because the NIH *must* give the respondents 30 days to provide their comments. And respondents generally do not respond immediately. After the NIH receives the responses, it must take time to review them, if its decision is not a foregone conclusion. The regulations grant a 60-day period to make a decision after the contractor or licensee responds.

To put these rules into context, in the highly unlikely event that the respondents submit their comments within five days of the notice, the NIH would still have 65 days to make its decision, leaving plenty of time for a hearing. If the respondents take a full 30 days to file their response, as is their right, then the NIH *could not possibly* complete its review within 30 days, and it would have up to 90 days to make its decision.

If the NIH decides to move forward, the regulations provide further procedural protections for respondents. If the NIH does not decide to move forward, the case terminates, and petitioners would have to appeal the NIH's decision, without a complete record of how it was reached.

Knowing the date on which the NIH sent notice of the petition to respondents would help the public better evaluate the fairness and reasonableness of its time frame, and there is no legitimate interest in withholding this information. Please clarify the date that the NIH sent notice of the petition to respondents.

Conclusion

I have demonstrated why the NIH has the authority to grant the procedures requested in this letter, and why a more transparent and fair process is necessary for the public to have any confidence that the NIH is giving meaningful consideration to the petition. A teleconference to further explore the issues raised in this letter would be beneficial. Keeping with the spirit of this letter, the conversation could be public, and Mr. Sawyer welcomes input from other stakeholders.

I can be reached at Kathryn.Ardizzone@keionline.org to arrange a meeting by Zoom or any other platform.

Please also confirm that all communications to the email address, SciencePolicy@od.nih.gov, will be posted online for public review in a timely manner.

Sincerely,

/s/ Kathryn Ardizzone
Kathryn Ardizzone, Esq.

Counsel for Petitioner Eric L. Sawyer