

BEFORE THE  
DEPARTMENT OF HEALTH CARE ACCESS AND INFORMATION  
STATE OF CALIFORNIA

In the Matter of the Penalty Issued to:

**ACELLA PHARMACEUTICALS,  
LLC**

Appellant.

HCAI No. 20-039-Q1

**DECISION OF THE DIRECTOR**

This appeal of a penalty assessment under Health and Safety Code section 127679 came before Elizabeth A. Landsberg, the Director of the California Department of Health Care Access and Information (“Director”), for decision following the Director’s review and rejection of the proposed decision prepared by the Hearing Officer. The Director independently reviewed the hearing record, including the video recording of the hearing and the exhibits. For the reasons provided below, the Director concludes that the Appellant, Acella Pharmaceuticals, LLC, established good cause for a reduction of the penalty assessment.

**HEARING AND RECORD**

This matter was originally heard before Michelle Church-Reeves, Hearing Officer, Department of Health Care Access and Information (“HCAI”), successor to the Office of Statewide Health Planning and Development (“OSHPD”),<sup>1</sup> State of California, on Tuesday, February 9, 2021 beginning at 10:31 a.m. PST.

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<sup>1</sup> Health & Saf. Code, § 127002.

HCAI was represented by managers of HCAI's Cost Transparency in Prescription Drug Pricing Program ("CTRx"), Ty Christensen, Health Program Audit Manager II, Accounting and Reporting Systems Section, and Chaz Chung, Staff Services Manager I.

Acella Pharmaceuticals, LLC, manufacturer of Ciclopirox Treatment Kits, "Appellant," was represented by Chris Schwab, Vice President and General Counsel for Acella Pharmaceuticals, LLC.

Both documentary and testamentary evidence was received. The matter was submitted for decision and the record was closed on Tuesday, February 9, 2021 at 11:08 a.m. PST.

#### PROCEDURAL FINDINGS

1. On November 16, 2020, HCAI assessed a penalty against Appellant in the amount of \$182,000 for its delinquent quarterly Wholesale Acquisition Cost ("WAC") Increase Report.
2. Appellant appealed the penalty by submitting a Request for Administrative Hearing form dated December 3, 2020 and received by the Hearing Office on December 3, 2020.
3. Appellant submitted its appeals within the required thirty days from the date of the penalty notice.<sup>2</sup>
4. The hearing was originally scheduled for January 25, 2021. The hearing was continued due to the Hearing Officer being on military leave. No party objected to the rescheduling of the hearing.
5. The hearing was held electronically using videoconferencing at the election of the Hearing Office. No party requested an in-person hearing or objected to an electronic hearing.
6. HCAI representatives submitted written exhibits to the Hearing Office and Appellant in advance of the hearing in a timely manner. Exhibits 1 through 12 were found to be authentic and relevant and admitted to the record.

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<sup>2</sup> Health & Saf. Code, § 127681(f).

7. Appellant submitted a written exhibit to the Hearing Office and HCAI representatives in advance of the hearing. Exhibit A was found to be authentic and relevant and admitted to the record.

#### FACTUAL FINDINGS

1. On or about August 18, 2020, Appellant registered with the CTRx Program.
2. On or about October 29, 2020, Appellant submitted a timely WAC Increase Quarterly Report for the third quarter, which is not at issue. Mr. Chung noticed that Appellant's 5-year price history included a price increase on or about January 3, 2020 from the quarter at issue, which had not been reported, and communicated this to Appellant.
3. On or about October 29, 2020, Appellant submitted the WAC Increase Quarterly Report at issue.
4. Appellant was required under Health and Safety Code section 127679 to file its WAC Increase Quarterly Report by April 30, 2020.<sup>3</sup> Penalties accrued from May 1, 2020 until October 29, 2020 when the report was filed.
5. In accordance with Health and Safety Code section 127679, subsection (e), HCAI assessed penalties in the amount of \$1,000 per day for 182 days, resulting in a total penalty amount of \$182,000.<sup>4</sup>
6. These facts were substantiated both by oral statements made under oath by Mr. Christensen at the hearing and written exhibits.
7. Under Health and Safety Code section 127679, subsection (f), a penalty may "be reviewed on appeal, and the penalty may be reduced or waived for good cause."
8. Appellant submitted a written statement with its appeal and made oral statements of facts it believes show good cause why its reports were not submitted in a timely manner.
9. Appellant testified that it moved locations in or around 2019 and did not receive the CTRx Notice of Proposed Rulemaking despite mail forwarding. However, Appellant knew it needed to expand its compliance division as staff were already overextended and hire an

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<sup>3</sup> See also Cal. Code Regs., tit. 22, § 96071.

<sup>4</sup> Health & Saf. Code, § 127679. See also Cal. Code Regs., tit. 22, § 96080.

executive who was able to focus and oversee staff to ensure all reporting requirements were met across multiple states. Appellant was in the process of hiring a Director of Compliance in March of 2020. Unfortunately, the individual accepted a competing offer, and the following week emergency declarations and stay-at-home orders began in response to the COVID-19 pandemic. Due to the disruption caused during this same time by the COVID-19 pandemic and its associated stay-at-home orders, travel restrictions, business impacts, and impacts to the labor pool, Appellant was unable to fill the position until September of 2020. Appellant was unaware of the CTRx Program prior to 2020, but even after it became aware of the CTRx Program, it did not immediately realize that any of its earlier WAC price increases were over the threshold and required reporting. The report at issue was for an increase of \$46 and Appellant was not yet familiar with the threshold calculations. However, Appellant, through its new Director of Compliance, attempted to comply with the CTRx statutes and regulations by filing a report it knew was due on October 29, 2020. Appellant planned to work back through its price increases to ensure a report had not been missed, however, before it could do so, Mr. Chung notified Appellant that it may have missed a report from an earlier quarter. Appellant immediately began working on the report at issue and submitted it the same day.

10. The drug at issue is a treatment for toenail fungus. 211 kits were sold in the state of California during 2020 for total gross sales of \$72,788. During the period at issue, between April 30, 2020 and October 29, 2020, Appellant's gross sales in California totaled approximately \$38,622.19 (these figures include reported sales from May-October, with October applied based on a daily amortization through the 29<sup>th</sup>).

11. These facts were substantiated by oral statements made under oath by Mr. Schwab and written exhibits.

12. The initial statements of both parties were not rebutted.

13. HCAI's representative confirmed that Appellant's subsequent reports have been filed timely.

#### DISCUSSION AND LEGAL CONCLUSIONS

The issue here is whether Appellant had good cause, as required by Health and Safety

Code section 127679, for failing to file Acella Pharmaceutical's quarterly WAC Increase Report by April 30, 2020 and whether the penalty should be waived in whole or in part. The burden rests on Appellant to submit evidence demonstrating good cause for a reduction of the penalty.

1. In *Waters v. Superior Court*, the California Supreme Court stated that, "good cause may be equated to a good reason for a party's failure to perform that specific requirement from which he seeks to be excused."<sup>5</sup> Good cause must be directly related to the specific legal requirement which the party failed to perform and should be outside the reasonable control of the party.<sup>6</sup>

Good cause is sometimes defined as circumstances beyond the party's control, and not related to the party's own negligent act or failure to act. On an individual basis, courts and administrative bodies have often found that hospitalization, incapacitation, accident involvement, or loss or unavailability of records may constitute good cause.<sup>7</sup> However, good cause is not limited to the listed reasons. The determination of good cause in a particular context should utilize common sense based upon the totality of the circumstances, including the purpose of the underlying statutory scheme.<sup>8</sup>

2. Appellant explained that it was unaware of the CTRx Program at the time of the reportable WAC increase in the first quarter of 2020 but took prompt action to provide compliance reporting once it became aware of the program approximately six months later. Mere ignorance is not a strong showing of good cause.<sup>9</sup> The Appellant's prompt response upon becoming aware of the CTRx Program was prudent, but it does not show good cause for its failure to file timely reports alone. A party's diligence is a factor in determining good cause for an extension or a delay.<sup>10</sup> While Appellant explains some of the difficulties it encountered in growing its compliance department, especially during the COVID-19 pandemic, Appellant does not explain why its compliance department remained unaware of the CTRx Program two years

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<sup>5</sup> *Waters v. Super. Ct. of Los Angeles County* (1962), 58 Cal.2d 885, 893 (hereafter *Waters*).

<sup>6</sup> *Ibid.*

<sup>7</sup> Fair Political Practices Commission, Guidelines for Waiving Late Fines (Nov. 2017) <http://www.fppc.ca.gov/content/dam/fppc/NS-Documents/TAD/FilingOfficer/700FO-Folder/Late%20Fine%20Guidelines.pdf> [as of December 4, 2019]. See also *Waters, supra*, 58 Cal.2d 885, 893.

<sup>8</sup> *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

<sup>9</sup> *Tsingaris v. State of California* (1979) 91 Cal.App.3d 312, 314.

<sup>10</sup> *People v. Financial Casualty & Surety, Inc.* (2016) 2 Cal.5th 35, 45. See also *Wang v. Unemployment Ins. Appeals Bd.* (1990) 225 Cal.App.3d 412, 420.

after the bill creating it was signed, or what actions its compliance department took during that time to stay apprised of regulatory developments.

3. The larger extenuating circumstances created by the COVID-19 pandemic and outside of the Appellant's reasonable control can be considered in assessing good cause for a waiver of the penalty. The substantiated facts show that at the time Appellant was attempting to expand its compliance department, and especially to hire a Director of Compliance, the COVID-19 pandemic was causing states to implement stay-at-home orders and heavily impacting businesses who had not yet adjusted to a remote work business model.

4. In response to the disruptions caused by the COVID-19 pandemic, many state and federal agencies issued extensions and penalty waivers for everything from reports to tax filings, typically ranging from 30 to 90 days.<sup>11</sup> While an extension was not available to Appellant, Appellant's testimony indicates that operations were heavily impacted by COVID-19 and the Georgia stay-at-home orders and the associated business and labor disruptions, factors which were clearly outside the control of Appellant. However, Appellant knew of the existence of the reporting requirements in the first quarter of 2020 and did not offer testimony which offered a specific timeline of the difficulties it experienced between March and September of 2020 or offer facts which explain how the business difficulties it encountered prevented compliance with the known reporting requirements. For that reason, appellant does not qualify for a waiver based on extenuating circumstances caused by COVID-19.

5. Appellant further argued that the penalties were excessive based off its total 2020 sales as the penalties exceed both Appellant's net and gross sales in California during the year, let alone the quarter at issue. The civil penalties assessed against Appellant are as required by the CTRx statutes and are not grossly disproportional to the quantifiable harm.<sup>12</sup> However, good cause

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<sup>11</sup> See, e.g., IRS Notice 2020-18, IRS Notice 2020-20, IRS Notice 2020-23; *see also* Executive Order N-55-20 (April 22, 2020). HCAI issued 90-day extensions for its Health Data and Advisory Council Consolidation Act reports, but extensions were not offered for the CTRx program reports which are mandated only if and when a manufacturer sufficiently increases a WAC price or releases a new product at a sufficient WAC price.

<sup>12</sup> *City and County of San Francisco v. Sainez* (2000) 77 Cal.App.4th 1302, 1322. A civil penalty, by virtue of its partially punitive purpose, is a fine for purposes of constitutional protection. So, the question is whether it is excessive, which is evaluated under the principle of proportionality. In imposing a fine, ability to pay becomes a factor.

may exist considering common sense and the underlying purpose of the statutory scheme,<sup>13</sup> even if the penalties are not prohibitive. The purpose of the fine is to incentivize compliance with the reporting requirements of the statute. The potential benefit that a company derives by skirting the reporting requirement is reflected in the company's increase in net sales as a result of nonreporting. That exact number is difficult to quantify but, by definition, the company's increase in net sales is strictly less than the company's gross sales of the product. In most cases that difference is vast. Barring abnormal circumstances, a penalty in the amount of the offender's gross sales is more than sufficient to incentivize compliance with the statute.

6. In this case, appellant sold 211 units in 2020, with approximate gross sales of \$38,622.19 from April 30, 2020, through October 29, 2020. This amounts to average daily gross sales of \$212.21 during the 182 days that the report was late, whereas Appellant was fined \$1,000 per day. Here, the penalties exceed Appellant's gross sales into the state by approximately five times, well beyond the expectation of what would be sufficient to incentivize reporting compliance under the CTRx program given the limited sales. Appellant has also recognized and does not contest its reporting obligations under the CTRx program in this instance and in the future and appears to have acted in good faith. Therefore, the substantiated facts show good cause for the reduction of the penalty.

#### CONCLUSION

For the reasons set forth above, Appellant has established good cause for reduction of the assessed penalty on the failure to report a WAC increase on the Ciclopirox Treatment Kits to 21.21% of the original penalty for a total penalty of \$36,290.80.

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<sup>13</sup> *Laraway v. Sutro & Co.* (2002) 96 Cal.App.4th 266, 274.

ORDER

The assessed penalty is reduced for good cause. \$36,290.80 of the penalty is upheld.

Dated: January 14, 2022

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ELIZABETH A. LANDSBERG

Director

Department of Health Care Access and Information