[redacted]

Helsinki, 24 April 2018

[redacted]

Copy to:

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[redacted]

Decision number:
Dispute reference number:
EC number of the substance:

DECISION ON A DISPUTE RELATED TO THE SHARING OF DATA

a) Decision

Based on Article 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')[2],

ECHA does not grant you the permission to refer to the information you requested from the Existing Registrant of the above-mentioned substance.

The reasons of this decision are set out in Annex I.

The present decision will be published in an anonymised version on ECHA's website[3].

[1] Pursuant to Article 8 of the REACH Regulation.

[2] Regulation (EC) N° 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, OJ L 396, 30.12.2006, p.1, as last amended.

[3] Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

[redacted]

b) Procedural history

On 28 February 2018[4], you ('the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] represented by [redacted] as their only representative ('the Other Party'), as well as the related documentary evidence to ECHA. To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 3 April 2018.

c) Recommendation

Under Article 27 of the REACH Regulation and the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')[5], the parties must still make every effort to reach an agreement on the sharing of the information. Therefore, the parties should continue to negotiate in order to reach an agreement that will be satisfactory for both parties. If the future negotiations fail again, the Claimant is free to submit another claim, covering the efforts that occurred after the submission date of the dispute claim leading to the present decision (i.e. 28 February 2018).

Advice and further observations are provided in Annex II.

d) Appeal

Either party may appeal this decision to the Board of Appeal of ECHA within three months of its notification. The appeal must set out the grounds of appeal. If an appeal is submitted, this decision will be suspended. Further details, including the appeal fee, are described at http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

Christel Schilliger-Musset[6]

Director of Registration

[4] You initially submitted your claim to ECHA on 28 February 2018. In order to ensure the application of the adequate procedure to your claim, ECHA asked for confirmation that this claim was submitted under Article 27(5) of the REACH Regulation. Following your clarification on 12 March 2018, ECHA began to process your claim.

[5] Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ* L 3, 6.1.2016, p.41.

[6] As this is an electronic document, it is not physically signed. This decision has been approved according to the ECHA's internal decision-approval process.

[redacted]

Annex I: REASONS OF THE DECISION

A. Applicable law

According to Article 11 of the REACH Regulation, all registrants of the same substance must submit information jointly. This obligation is confirmed by Article 3(1) of the Commission Implementing Regulation, which requires ECHA to ensure that all registrants of the same substance are part of the same joint submission for the substance.

Article 27(1) of the REACH Regulation provides that should there exist an earlier registration on the same substance, a potential registrant shall request information from the existing registrant(s) on tests conducted on vertebrate animals, and may request information on tests not conducted on vertebrate animals. When such a request has been made, Article 27(2) and Article 27(3) of the REACH Regulation require existing registrants and potential registrants to make every effort to reach an agreement and to ensure that the costs of sharing the information required for registration are determined in a fair, transparent and non-discriminatory way. In this respect, the Commission Implementing Regulation further defines the principles necessary to ensure an efficient implementation of the data-sharing and joint submission obligations. The objective is to encourage and foster discussions among the registrants of the same substance in view of ensuring the quality of the dossier.

When a dispute brought to ECHA concerns the sharing of studies which have already been submitted to ECHA, Article 27(6) of the REACH Regulation requires ECHA to determine whether to grant a permission to refer to the information contained in the registration dossier, i.e. to the corresponding studies, subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).

In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the documentary evidence on the negotiations as provided by the parties, to establish whether the parties have made every effort to reach an agreement on sharing the information and the related costs in a fair, transparent and non-discriminatory way.

Making every effort means that the registrants must negotiate as constructively as possible and in good faith. They must make sure that the negotiations move forward in a timely manner, express their arguments and concerns, ask questions and reply to each other's arguments, concerns and questions. They must try to understand the other party's position and consider it in the negotiations. Making every effort also means that the parties need to be consistent in their negotiating strategy; they should raise their concerns in a timely manner and behave in a consistent and predictable manner as reliable negotiators. When they face a dissent on an aspect, the parties have to explore alternative routes and make suitable attempts to unblock the negotiations. As the potential and existing registrants themselves bear the obligation to make every effort to find an agreement, they need to exhaust all possible efforts before submitting a dispute to ECHA with the claim that the negotiations have failed.

B. Summary of facts

The negotiations as submitted to ECHA began with an email of 28 October 2016, sent from the representative of the Claimant (hereinafter together referred to as the 'Claimant') to the non-EU company, represented for the purpose of the REACH Regulation by an only representative ('OR') (hereinafter together referred to as the 'Other Party')[7]. The Claimant

[7] There seems to have been earlier discussions between the parties, which were not submitted to ECHA for the assessment of the present dispute claim.

[redacted]

referred to a teleconference the Parties had had earlier and invited the Other Party to tell them '*as soon as possible* [their] *decision and* [their] *new OR*'.[8] The Other Party shared the name of their new OR with the Claimant on 28 November 2016, and explained that the change was now complete.[9] On the next day the Claimant asked for '*more information and/or decision*' from the Other Party.[10]

On 25 September 2017, the Claimant contacted the Other Party again to ask whether they had discussed data-sharing with their new OR.[11] By an email of 25 September 2017, the Other Party indicated that they considered their own substance [redacted], therefore different from the Claimant's substance.[12]

On 7 November 2017, the Claimant provided the Other Party with a reply by ECHA to a question submitted by the Claimant to ECHA's Helpdesk. This reply referred to the result of the Claimant's inquiry, finding that the substance of the Other Party and the substance of the Claimant are to be part of the same joint submission, because [redacted]. The Claimant asked that '[s]*ince ECHA confirmed again the sameness of both substance identities, would* [the Other Party] *like to make* [a] *decision to share data/cost with* [the Claimant]'.[13]

On the following day, the Other Party indicated that they would contact their OR to get their opinion on the message sent by the Claimant. They also informed the Claimant that patents exist in relation to the substance the Claimant intends to register and gave the name of the company owning these patents (the 'patent owner'). They asked the Claimant to '*check* [the] *claims of the patents*' and explained that the Other Party is '*authorized by* [the patent owner] *to sell* [redacted] *which are within the scope of the above mentioned patent family* […] *to customers*'. The Other Party explained that if they were to share data on the substance with other manufacturers or importers in the European Union's area, they may lose their intellectual property rights related to the patents.[14]

On 1 December 2017, the Other Party informed the Claimant that they received comments from their OR. They indicated that they could not proceed with data-sharing because (1) the Claimant's substance '*undoubtedly infringes* […the] *Patents*' and (2) the substance of the Other Party and the substance of the Claimant '*are exclusively different and thus require separate registrations*'. The Other Party asked for comments from the Claimant on this issue, and advised that the Claimant '*has to dissolve the patent problem before the data sharing of the substance'*. The Other Party reiterated that if they were to share data with the Claimant, they may lose the intellectual property rights of the patent '*contrary to the [patent owner]'s intention*'. They further stated that they '*can not justify* [their] *action, as data-sharing without any obligation, to* [the patent owner]'.[15]

On 20 December 2017, the Claimant replied that '*after reading the patent, it is not found relevant to the current issue on the sameness of substance identity*'. They indicated their intention to lodge a data-sharing dispute to ECHA and asked for the name of a contact person

[8] Claimant; 28 October 2016
[9] Other Party; 28 November 2016
[10] Claimant; 29 November 2016
[11] Other Party; 25 September 2017
[12] Other Party; 25 September 2017
[13] Claimant; 7 November 2017
[14] Other Party; 8 November 2017
[15] Other Party; 1 December 2017

within the Other Party's OR.[16]

On the following day, the Other Party wrote that '[t]*hough* [the Claimant] *think*[s] *the patent is irrelevant on the sameness of substance identity on REACH,* [the Claimant] *need*[s] *to know* [for] *a fact that the substance is restricted by the patent law simultaneously*'. The Other Party further explained that '[they] *have* [been] *granted the nonexclusive license from the patent licenser, so* [they] *have to keep the obligation of the licensee based on the license contract*'. The Other Party asked to receive the opinion of the Claimant itself (i.e. not its representative) on the issue related to the patents. The Other Party gave the name and address of their OR, and indicated that they would provide the name of the contact person in their OR after obtaining the opinion of the Claimant itself on this issue.[17]

On 28 February 2018, the Claimant lodged a dispute to ECHA.

C. Assessment

During the negotiations, the Other Party raised first doubts as to the sameness of their substance with the Claimant's substance. After the Claimant shared a reply by ECHA's Helpdesk regarding the sameness on the two parties' substances, the Other Party raised concerns as to whether the Claimant's substance was covered by patents owned by another company. The Other Party referred to their contractual obligations with this patent owner and to the possible impact these would have on the Other Party's right to share data. They explained that, as a licensee with a non-exclusive license, they may lose their '*intellectual property rights of the patents*'[18] in case they were to share data on the substance with another company. During the negotiations, the Other Party repeatedly asked for comments from the Claimant regarding this concern.

The Claimant, however, only replied that they considered the patent(s) as not '*relevant to the current issue on the sameness of substance identity*'[19]. The Claimant did not provide any further indication on their situation nor on the reasons why the patent(s) would not be relevant to the negotiations with the Other Party. The Claimant also did not indicate that the Other Party's situation would not be clear to them, e.g. by requesting some clarifications on the patent(s) or on the terms of the Other Party's license contract with the patent owner. The Claimant did not reply to the last email sent by the Other Party, which asked for comments on that issue, and submitted a dispute to ECHA in February 2018 after remaining silent in the negotiations for two months.

Making every effort to find an agreement means that the negotiating parties must justify their position and reply to the concerns raised by their negotiating partner. Finding a common understanding on each party's position regarding the sharing of data is a prerequisite for entering into successful data-sharing negotiations. In particular, the contractual rights of an existing registrant to share data with a potential registrant may need to be clarified before starting the data-sharing negotiations, as also expressed in ECHA's Guidance on data-sharing[20]. In case an existing registrant would have doubts about its right to share data, this existing registrant must explain its position and open a discussion on that point with the potential registrant. In return, a potential registrant needs to reply to the questions raised by the existing registrant in this regard, in order to give to the existing registrant the opportunity

[16] Claimant; 20 December 2017

[17] Other Party; 21 December 2017

[18] Other Party; 1 December 2017

[19] Claimant; 20 December 2017

[20] Guidance on data-sharing (Version 3.1, January 2017), section 3.3.3.8., in particular pp. 66-67 (this section relates to data-sharing under Article 30, but reference is made to this section under section 4.7.1. of the Guidance related to sharing of data under Article 27).

[redacted]

to adequately assess the situation in light of their contractual rights and obligations and to adapt their stand if relevant.

In the negotiations, the Other Party raised their concerns regarding their right to share data based on their contract with the patent owner. They gave to the Claimant the name of the patent owner and the references to the patents and asked the Claimant to provide observations on that issue. By doing so, the Other Party made efforts to explain their position and they gave an opportunity to the Claimant to provide explanations as well.

During the negotiations, the Claimant also showed some efforts in the discussion on the substance sameness, by sharing with the Other Party a reply from ECHA's Helpdesk in relation to this substance sameness discussion. However, regarding the issue of their situation in relation to existing patent(s), the Claimant only replied that these patent(s) would not be relevant to the sameness of the substances. By doing so, the Claimant did not enter into a discussion on the specific issue raised by the Other Party and did not give the Other Party the opportunity to understand the Claimant's situation. Therefore, the Other Party was not in a position to assess how the sharing of data under the REACH Regulation with the Claimant would affect the Other Party's situation regarding the patent(s) and their license.

By refusing to discuss on an issue raised by the Other Party regarding their contractual rights and obligations in relation to the sharing of data, the Claimant did not allow the negotiations to progress. Therefore, the Claimant did not make every effort to find an agreement with the Other Party.

D. Conclusion

The Claimant did not make every effort to reach an agreement with the Other Party. Therefore, ECHA does not grant the Claimant permission to refer to the studies.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS[21]

ECHA recommends both parties to continue their negotiations to find an agreement on the sharing of data. The following points can be taken into account in order to facilitate the discussions.

Based on ECHA's understanding of the negotiations, ECHA advises the Claimant to consider:

- Clarifying to the Other Party what is their position regarding the patent(s) and the substance, in order to address the Other Party's concerns in that regard and to understand the Other Party's potential contractual limitations to share data for the purposes of REACH registration, and;
- Seeking, if necessary, clarifications on these issues.

ECHA also advises the Other Party to:

- Provide a reply to the questions that the Claimant may raise in the future of the negotiations, e.g. on the conditions under which the Other Party is entitled to share data and for which purpose;
- If necessary, facilitate the contacts between the Claimant and whomever may be in capacity to unlock the discussions or share data with the Claimant, especially in case (a) the owner of the data is a third party or (b) the Other Party is the data owner but is not entitled to share this data.

In addition, ECHA reminds both parties that substances covered by the same joint submission may still have distinct properties. Therefore, it may happen that some of the data relevant to one reported composition of a substance may not be relevant for another composition of the substance. In this case, a registrant may need to opt-out, under Article 11(3) of the REACH Regulation, for some or all of the endpoints and submit some data separately to fulfil those endpoints.

[21] Please note that this section does not contain elements that ECHA took into consideration in its assessment of the parties' efforts in their negotiations. ECHA's assessment of the dispute is set out only in the section 'C. Assessment' of Annex I. The Annex II 'Advice and Further Observations' aims only at providing further advice and information that can be helpful for the parties in the future of their discussions on data sharing and joint submission obligations.