

b. Recommendation

Under Article 27 of the REACH Regulation and the Implementing Regulation 2016/9, 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, the Claimant is free to submit another claim covering the efforts that occurred after the submission date of the dispute claim that lead to the present decision (i.e. 7 June 2018).

Advice and further observations are provided in Annex II.

c. 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 for appeal. If an appeal is submitted, this decision will be suspended. Further details, including the appeal fee, are set out at <http://echa.europa.eu/web/guest/regulations/appeals>.

Yours sincerely,

Christel Schilliger-Musset⁴

Director of Registration

⁴ 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.

Annex I: REASONS FOR THE DECISION

A. Applicable law

1. When a dispute is submitted to ECHA pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment of the Parties' efforts to reach an agreement (Article 5 of the Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of the Implementing Regulation 2016/9, ECHA may grant permission to refer to the requested studies, if the Claimant has made every effort to find an agreement on the sharing of the data and the access to the joint submission and the Other Party has failed to do so. The permission to refer is subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).
2. The obligation to make every effort to find an agreement that is fair, transparent and non-discriminatory is laid down in Articles 27(2) and 27(3) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Commission Implementing Regulation.
3. Making every effort means that the existing and potential 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 each other'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 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 negotiations have failed.
4. In particular, every effort means addressing the legitimate concerns brought up by the other company, and taking into considerations potential constraints to data-sharing posed by contractual obligations or intellectual property rights. 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.⁵ In case an existing registrant would have doubts about their right to share data, this existing registrant must explain their position and open a discussion on that point with the potential registrant. In turn, 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 to adequately assess the situation in light of their contractual rights and obligations and to adapt their stand if relevant.

B. Summary of facts

5. This summary of facts is based on the documentary evidence submitted by the Claimant on 7 June 2018 and by the Other Party on 29 June 2018.
6. The data-sharing negotiations between the Parties began on 28 October 2016. On 28 February 2018, the Claimant submitted a dispute claim with reference [REDACTED] against the Other Party. Consequently, ECHA assessed the efforts made by the Parties in the

⁵ 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).

negotiations upon until 28 February 2017 when the dispute was lodged, and on 24 April 2018, ECHA issued its decision [REDACTED] not granting the Claimant permission to refer to the requested information. The summary of facts concerning this first round of negotiations can be found in ECHA's above-mentioned decision.

7. On 14 May 2018, after ECHA had issued the above-mentioned decision, the Claimant informed the Other Party that they did *'not understand why the data sharing under REACH is forbidden due to [the Other Party's] patent(s)'*. They asked the Other Party to *'provide any written document to support [their] statement'* and to *'clarify the conditions under which [the Claimant] is entitled to share [the Other Party's] data for the purpose of registering [the Substance] under REACH as importer'*.⁶
8. On 29 May 2018, the Other Party referred to their earlier messages, explaining that *'as a licensee of patent [they] have obligations based on the licence contract'*, and therefore they were *'careful in case there is patent permission/infringement matter'*. They saw that the data-sharing negotiations and joint registration were *'totally possible'* if the Claimant could *'address this patent IP matter now [by] providing evidence to satisfy that the patent is either not violated or otherwise not applicable, or patent is respected by [an] actual non EU manufacturer'*.⁷
9. On 31 May 2018, after the Claimant had asked to receive the patent and the licence contract, and asked the Other Party to *'provide those documents as evidences and explain which clauses prevent the data-sharing under REACH'*,⁸ the Other Party wrote that they had already provided the patent name previously on 8 November 2017. They gave an internet link to access the patent online and explained that the patent was effective e.g. in [REDACTED]. Then the Other Party repeated their request made in the email on 29 May to receive evidence and recommended the Claimant to be in contact with the patent owner directly and dissolve the issue.⁹
10. The same day, the Claimant summarised the patent and its description, and asked the Other Party to *'correct [...] if there is any important point missing'*. The Claimant also stated that they could *'not find any text in the patent for protecting [REDACTED], [REDACTED] [and] [REDACTED] and [REDACTED] information of [the Substance] because [REDACTED]'*. The Claimant stated that [REDACTED] the Substance [REDACTED] protected by the patent was not the same as generating test data on the Substance. They asked the Other Party to tell if there is *'information [that] is protected by this patent'*, which the Parties could *'discuss to exclude'*, and asked, if there were any other related patents.¹⁰
11. In reply, the Other Party said that they did not understand the Claimant's argument, and asked, why the Claimant wanted to share [REDACTED] [and] [REDACTED] and [REDACTED] information in patent'. The Other Party reiterated that they had informed the Claimant from the beginning that if the substances were the same, the Claimant's substance *'will conflict'* with the patent and that the Other Party's *'substance [is] claimed in the patent and [that they] are a licensee'*. The Other Party recommended the Claimant to contact the patent owner to clarify, *'whether [the Claimant's] substance is in conflict with the patent'* or not. They explained that even though *'REACH is a regulation of the*

⁶ The Claimant; 14 May 2018

⁷ The Other Party; 29 May 2018

⁸ The Claimant; 29 May 2018 and on 30 May 2018

⁹ The Other Party; 31 May 2018

¹⁰ The Claimant; 31 May 2018

EU, patent is enacted by law, particularly [the] ██████████ patent law' and that 'the spirit/purpose of [the two statutes] is different'.¹¹

12. The Claimant explained that the data they wanted the Other Party to share with them is required by REACH for registration. The Claimant also wrote that the substance 'identity, composition and production technology, protected by [the Other Party's] patent, are different from the information to be shared'. In their view, knowing the Other Party's substance identity was 'not necessary', as 'ECHA [...] made judgement that [the] substances are same' and 're-confirmed it'. Regarding contacting the patent owner, the Claimant stated that they followed 'all European Laws' and had checked the patent and found 'no conflict'. They asked the Other Party to 'validate [their] statement' that the patent in question covered the data to be shared, because in their view, the information was 'not part of the claims of [the] patent [...] strongly supporting the conclusion that [the] information [is] not protected by [the] patent, and should be shared under REACH'. The Claimant further argued, that if a company registering first '[would refuse] to share the information saying simply his substance is protected by his own patent without evidence, [they would] block the registration of other manufacturers'. Consequently, the 'REACH regulation [would be] used as a tool to set up trade barrier against other competitors'. The Claimant stated that they would 'have to revert back to ECHA for judgement'.¹²
13. On 4 June, the Other Party told that 'the information of the substance [...] can be referred easily from other enormous literature in public domain'. They pointed out that an importer would be liable if the substance they import would be manufactured by infringing a patent. They inquired, when ECHA re-confirmed substance sameness and asked to receive 'a formal decision/information'.¹³
14. The same day, the only representative of the non-EU manufacturer [hereinafter 'Other Party'] took over the negotiations from the Other Party's side and continued that in its helpdesk reply to the Claimant,¹⁴ ECHA did not re-assess the substance sameness but 'simply explained the bases of coming to their decision at the time they assessed [the Claimant's] substance'. They argued that 'ECHA still accepted the status that [the Other Party's] substance is actually a ██████████ (different CAS identifier)', but that substance sameness question was 'debatable'. The Other Party explained that 'IP (patent/licence) and REACH are separate matters [...] yet in this case somewhat intertwined due to ██████████'. The Other Party found the Claimant's statement that they did not find a conflict with the patent 'insufficient to clarify the matter [...] without any other supporting evidences or explanation'. Furthermore, the Other Party agreed that the 'intrinsic study data in the registration itself [was not] patent protected' but argued further that 'the substance covered by the registration is covered within the scope of patent and [the Other Party, i.e. the non-EU manufacturer] is valid licensee [who therefore] has to be cautious'.¹⁵
15. The Other Party proposed further that the Claimant should go back to ECHA's recommendations in the first decision, and to 'engage with the relevant people: discuss the matter directly with the [Claimant's] non EU supplier/manufacturer(s), chemists and or directly with the patent owner [or] consult with a IP specialist', to 'gather the necessary

¹¹ The Other Party; 1 June 2018

¹² The Claimant; 1 June 2018

¹³ The Other Party; 4 June 2018, message by the non-EU manufacturer

¹⁴ On 11 July 2017, during the negotiations assessed in the decision ██████████, the Claimant shared with the Other Party ECHA's reply to the Claimant's helpdesk question with the reference ██████████

¹⁵ The Other Party ; 4 June 2018, message by the OR

evidence and then present this to [the Other Party]'.¹⁶

16. The same day, the Claimant summarised that ECHA had confirmed substance sameness, and that the information they wanted access to was not *'patent protected'*. They argued that the Other Party wanted *'all other registrants [to] get permission from [the] patent owner to manufacture or import, before'* data sharing, repeating that they respected the law and pointing out that authorities make the judgement on potential breaches of law, not other registrants. The Claimant stated they would *'submit the [...] summary to ECHA for judgement'*¹⁷
17. On 5 June 2018, the Other Party wrote that *'the compositions [of the substances] differ'* but *'tentatively quite possibly'* they could register under the same *'broad non confidential [joint submission] boundary composition'*, or *'reporting even two separate [joint submission] boundary compositions'* and *'[e]ach company then submitting individually their exact composition, and any confidential details'*, or making an opt-out. They confirmed that the information in question was not covered by the patent, but that the access to it *'should be agreed with the data owner [and] duly compensated'*. They explained that contacting the patent owner was one suggestion, in order to *'present some evidence if there are patent infringement issues'* so that the Other Party could be *'assured [that] they are not in trouble as [a] licensee'*, which *'ECHA agreed is [a] valid concern'* in its previous decision. The Other Party asked the Claimant to *'give [the Other Party] something, anything that can help [them]'* as evidence, and stated that filing a new dispute was *'premature'*.¹⁸
18. The Claimant argued in turn that they had made *'all efforts to explain [...] why the patent is not relevant to data sharing under REACH and why [they] urge the lead registrant to share data for the registration purpose only'*. They repeated that the potential registrant will respect patent law if they decide to import, but that *'by law [the Claimant] has no obligation to guarantee anything to another registrant for the purpose of REACH registration'*, and that a lead registrant must not *'block other co-registration [and] impose self-defined pre-condition'* to data-sharing. They saw that the negotiations were *'deadlocked'*, and they would refer the matter to ECHA.¹⁹
19. On 6 June 2018, the Other Party repeated their previous arguments but also proposed that the Claimant *'could have presented some evidence of their due diligence efforts in sourcing the product (substance) and provide a simple written statement [to the Other Party and the patent owner] to declare [that] there is [and] or will be no patent conflict [...] either by [the Claimant's] suppliers or in their own capacity of importer'*, offering to prepare the document. The Other Party asked, *'why invest so much trouble and cost in registering this substance before due care to this important matter'*, as the *'existing patent claim undoubtedly concerns in the embodiment, [REDACTED] the substance represented and defined by CAS [REDACTED], so it is fair to perceive it is intertwined with a substance registration and so [the Other Party is] entitled to expect some discussion and explanation from the potential coregistrant'*. They told that the patent owner was informed and might contact the Claimant directly.²⁰
20. On 7 June 2018, the Claimant, referring to a phone call, wrote that they were *'not at a position to satisfy [the] demand or pre-condition imposed by LR for data sharing'* as law does not require them to provide a statement the Other Party suggested. The Claimant argued that

¹⁶ *Ibid.*

¹⁷ The Claimant; 4 June 2018

¹⁸ The Other Party; 5 June 2018

¹⁹ The Claimant; 5 June 2018

²⁰ The Other Party; 6 June 2018

such a statement would imply that the Other Party's 'rights related to [REDACTED] can be extended to, or grant the rights of refusing sharing data under REACH'. It would also mean that the Other Party would 'have gotten rights as LR [lead registrant] to censor other co-registrants' compliance in commercial activity [...], even though the commercial activity doesn't exist [...] refusing data-sharing to leverage it'. The Claimant repeated their earlier question that 'based on which clauses of patent law [or] REACH regulation' could the Other Party justify their demands'.²¹

21. The Claimant stated that data sharing under REACH would not cause a 'risk for [the Other Party] on patent infringement, because data sharing does not replace registration, importation and patent infringement during importation', in particular because the patent did not cover said information, as confirmed by the Other Party. The Claimant repeated that in case they would register, 'there is still long way' to actually import the Substance. The Claimant wrote that they would refer to ECHA 'to avoid any further on-purpose delay'.²²
22. The same day, the Other Party agreed that their 'terms and suggestions [...] would be entirely voluntary', but that what they suggested was 'quite reasonable and much easier faster and preferable (for both parties) and [would] offer a much higher probability of a positive outcome'. They pointed out that, even after a registration, the Claimant would have to be prepared to respect intellectual property rights. Finally, the Other Party asked for a week for internal discussion too see 'if [it would be] possible [to] start at least with "drafting" terms [for] a Joint Submission agreement (in parallel to other matters)'. They asked, what would be 'a reasonable period to prepare and share any draft SIEF JS data & cost sharing agreement', pointing out that the Claimant could file a new dispute if that would elapse.²³
23. On 7 June 2018, the Claimant submitted a claim under Article 27 of the REACH Regulation concerning the failure to reach an agreement on the sharing of information with the Other Party.

C. Assessment

24. As explained in section A, ECHA assesses the overall efforts made by the Parties in the negotiations, including the efforts outlined in section B of the present decision and the previous efforts assessed in the decision [REDACTED]. Therefore, the present decision is taking into account all the communications provided by the Parties. However, as part of the efforts have already been assessed in the previous decision, the factual background and the assessment of the present decision mostly focus on the efforts that have not been assessed in the previous decision.

The patent-related concerns in the data-sharing negotiations

25. As discussed in the previous data-sharing decision [REDACTED], the Other Party is a licensee of another company who holds a patent connected to the Substance.
26. Throughout the negotiations assessed in the previous and the present decision, the Other Party raised concerns about their contractual obligations in relation to the license agreement with the patent holder, which would potentially limit their rights in the data-sharing negotiations. The Other Party explained, that they could not share information in their

²¹ The Claimant; 7 June 2018

²² *Ibid.*

²³ The Other Party; 7 June 2018

registration dossier without some confirmation that either the potential registrant and their suppliers are respecting the patent, or that the patent would not apply to the potential registrant's substance.

27. In its previous decision [REDACTED], ECHA acknowledged this situation and the potential constraints, in particular the contractual obligations of the Other Party in relation to the license agreement with the patent holder. ECHA advised the Parties to clarify their situations in the context of the patent, in order to solve this issue and move forward in the data-sharing negotiations. To make every effort to reach an agreement on sharing of data and related costs, the Parties should make efforts to understand and to address the potential constraints stemming from the Other Party's license agreement with the patent holder.
28. ECHA notes that in the negotiations outlined in section B of the present decision, both Parties sought mutual understanding and provided further information on their positions by asking questions, by replying to the claims made by the other company, and by justifying their own views. In this regard, ECHA considers that both Parties made some efforts to progress the negotiations as recommended by ECHA in its previous decision.
29. In particular, the Claimant made efforts to understand the patent and the Other Party's potential constraints under the license agreement with the patent holder. The Claimant asked to receive the relevant patent and licence agreement, summarised the patent claims and description, asked the Other Party to pinpoint the relevant provisions, and asked, if there were other related patents. Furthermore, the Claimant proposed to exclude confidential information from their data-sharing discussions. The Claimant also explained their position as a potential importer.
30. In turn, the Other Party made efforts by proposing possible actions that the Claimant could undertake to clarify whether or not their substance was related to the patent in question.
31. The Other Party made further efforts by explaining that despite the abovementioned efforts by the Claimant, there was still no confirmation, if the Claimant infringed the patent in question or not. Thus, the Other Party could not be sure if sharing data with the Claimant affected their contractual obligations as a licensee.

The solutions proposed by the Other Party

32. During the negotiations, the Other Party proposed solutions to the Claimant on how to register together without breaching the contractual obligations as licensee. On 29 May 2018, the Other Party asked the Claimant to '*provid[e] evidence to satisfy that the patent is either not violated or otherwise not applicable, or patent is respected by actual non EU 'manufacturer'.*'²⁴ On 31 May 2018, they '*recommend[ed] [the Claimant] to contact the patent owner directly.*'²⁵ On 5 June 2018, the Other Party proposed to '*register [...] together with a broad non confidential [joint submission] boundary composition*', or with '*two separate [joint submission] boundary compositions*' to solve the open questions regarding the sameness of the substances. Then, '*each company could submit individually their own exact composition, and any confidential details*'. The Other Party saw that also an opt-out could be possible.²⁶ Finally, on 6 June 2018, the Other Party suggested that the Claimant would present '*some evidence of their due diligence efforts in sourcing the product (substance) and provide a simple written statement [...], to declare there is & or will be no patent conflict*'. This way, the Other Party would have

²⁴ The Other Party; 29 May 2018

²⁵ The Other Party; 31 May 2018

²⁶ The Other Party; 5 June 2018

the guarantee that the Claimant and their suppliers would not jeopardise the Other Party's contractual obligations under the license agreement.²⁷

33. By making proposals on how the Claimant could address the Other Party's concern and how the negotiations could be unlocked, the Other Party made efforts to reach an agreement.
34. The Claimant did not follow any of the above-mentioned proposals from the Other Party. The Claimant merely stated that they did not see any conflict with the patent, and that they and their manufacturers followed all effective legislation. They explained that data-sharing, registration under REACH, and import of a substance were not the same thing. As the patent did not cover the data they wanted to share, they did not see any risk of patent infringement in sharing the data under REACH. The Claimant explained that they would possibly import the Substance in the future, in which case it would be up to competent authorities, not other REACH registrants, to inspect a potential patent infringement.
35. Concerning the Other Party's proposal of a written statement, the Claimant stated on 7 June 2018 that '[they were] *not at a position to satisfy* [the Other Party's] *demand or pre-condition imposed by LR for data-sharing*'.²⁸ The Claimant further argued that they were not obliged by law to provide the suggested signed statement to the Other Party in order to register, and that setting pre-conditions to data-sharing was not in compliance with REACH. They stated that in effect, the Other Party was blocking other companies from entering the market.
36. ECHA recognises that Article 27 of REACH does not foresee pre-conditions to data-sharing. In addition, ECHA does not have the competence to establish a breach of contractual arrangements e.g. in relation to a license agreement. Notwithstanding, Article 27 of REACH provides that the Parties have the obligation to make every effort to reach an agreement on sharing of data and related costs in a fair, transparent and non-discriminatory way. Part of making every effort is that the negotiating parties need to make their concerns known to the other company and address the other company's concerns in a constructive way.
37. The Other Party raised consistently a concern related to their contractual obligations under the license agreement and a potential infringement of intellectual property rights, explained the reasons for these concerns, and proposed a number of solutions to progress the negotiations.
38. After their first suggestion to exclude confidential information from data-sharing, the Claimant did not make any other proposals to address the Other Party's concerns related to the license agreement and intellectual property rights, and to solve the matter in a constructive way. The Claimant merely asserted repeatedly that the patent was irrelevant for data-sharing. The Claimant rejected the Other Party's alternative proposals to address any patent-related concerns, even if this would have made the negotiations move forward. Moreover, they did not justify their refusal with tangible evidence, when requested by the Other Party.
39. ECHA notes that the Claimant rejected the potential risk of the Other Party to breach their contract as a patent licensee as a legitimate concern. The Claimant merely stated that the patent is irrelevant to data-sharing because the information they wanted to share is not covered in by the patent in question and therefore there is no obstacle in sharing it. The Claimant refused to engage in a constructive exchange about the Other Party's concerns and their contractual rights and obligations.
40. The Claimant could have offered alternative solutions, asked questions about the Other Party's

²⁷ The Other Party; 6 June 2018

²⁸ The Claimant; 7 June 2018

proposals and contest, in a constructive way, the proposed solutions. By refusing to discuss a way forward, which would have been consensual to both Parties and would have eased the Other Party's concerns regarding their position as a licence holder, the Claimant ignored a concern raised by the Other Party and failed to make every effort to reach an agreement.

The rights of the Other Party to share the data

41. The Claimant requested access to some information in the Other Party's dossier. The Other Party told on 4 June 2018 that the requested information *'can be referred easily from enormous literature in public domain'*. Further, on 5 June 2018, the Other Party confirmed that the information in question is not covered by the patent, arguing the same time, however, that *'permission [and] right to use [the data] or refer to the information in the registration should be agreed with the data owner, and data owner duly compensated'*²⁹.
42. ECHA notes that the discussions on sharing of data are short, because the Other Party did not want to discuss this matter before their other concerns were addressed. After the Other Party had confirmed that the data required for REACH registration was not covered by the patent in question, the Claimant concluded that the patent was not relevant for sharing this information.
43. However, it is not clear from the negotiations, whether or not the Other Party has the right to negotiate sharing of the data, according to their contractual obligations³⁰. The Claimant asked clarifications and evidence on the matter. Despite this, the Other Party never clarified their rights to share the data nor replied to the Claimant's request for an explanation. Therefore, the Other Party did not make every effort to explain to the Claimant if they were entitled to share the data and if not, for which reasons.

Substance sameness and joint submission

44. ECHA notes that during the entire negotiations, the Parties referred to the questions on whether or not their substances were the same in the meaning of REACH.
45. The Claimant based their data-sharing requests on ECHA's assessment in the context of their inquiry. The Claimant justified that they did not need to know the identity of the Other Party's substance, since ECHA had assessed in the inquiry, and maintained in their helpdesk reply, that both substances would be covered by the same numerical identifier.
46. In turn, the Other Party challenged the substance sameness, asking first on 4 June 2018 the Claimant to provide an official decision where ECHA re-confirmed that the substances are the same. They further argued that ECHA had not re-confirmed substance sameness in the helpdesk reply, only explained their earlier reasoning, which led them to the inquiry conclusion. In the negotiations assessed in the decision [REDACTED], the Other Party stated that the substances are not the same, and on 5 June 2018, they maintained that *'the compositions differ ([REDACTED] vs [REDACTED])'*³¹. However, the same day they were ready to see the substances registered together.³² Moreover, on 7 June 2018, the Other Party proposed that they would try to draft provisions for a joint submission agreement, in parallel to the discussions on other topics.
47. ECHA notes that, despite the potentially different compositions, and despite initially being

²⁹ The Other Party; 5 June 2018

³⁰ The Other Party; 8 November 2017, 1 December 2017; see also ECHA's decision in the previous dispute claim

³¹ The Other Party; 4 June 2018, message from the OR

³² The Other Party; 5 June 2018

reluctant to discuss the matter, the Other Party made efforts to attempt to progress registering the two substances together. The Claimant made efforts as well by explaining their view, making also reference to ECHA's inquiry letter as well as requesting clarification from ECHA's helpdesk and sharing it with the Other Party.

48. However, ECHA notes that by the time the present dispute was filed, the Parties still did not have an agreement on the sameness of the substances.
49. Agreeing on substance sameness is a prerequisite for sharing of data and registering together under REACH. ECHA considers that despite the initial resistance by the Other Party, negotiations on substance sameness and joint registration were progressing, and both Parties should continue their efforts towards reaching an agreement in this regard.

Filing the dispute before the negotiations reached a standstill

50. Finally, during the present negotiations, the Claimant repeatedly told that they would file a new dispute, not demonstrating willingness to continue with the negotiations. In addition, they did not reply to the email on 7 June 2018, in which the Other Party asked for seven days to discuss internally the possibility to draft contractual provisions for a joint submission agreement. Therefore, the Claimant filed the dispute when the negotiations had not reached a standstill, and not as a last resort.

A. Conclusion

51. Overall, the Claimant has made efforts to determine the contractual obligations of the Other Party in relation to the patent in question, in order to understand their rights and limitations to share data. However, the Claimant did not make every effort to reach an agreement on the sharing of information, as they did not address the Other Party's concerns related to their contractual obligations; did not follow any of the proposals offered by the Other Party to solve the issue or did not offer constructive alternatives to address the Other Party's concerns; and filed the dispute before the negotiations had reached a standstill.
52. In turn, the Other Party made efforts by clarifying their concerns in relation to the patent, by proposing different pragmatic options to accommodate their concerns in this regards, as well as by suggesting to move ahead with joint submission discussions in parallel to the discussions related to the patent.
53. Therefore, ECHA does not grant the Claimant permission to refer to the studies.

Annex II: ADVICE AND FURTHER OBSERVATIONS³³

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.

- It is the negotiation parties' responsibility to agree on a mutually acceptable way of ensuring that the concerns of the parties are addressed. In order to find an agreement for data-sharing, the Parties should take into consideration two objectives; helping the Claimant to complete the registration under REACH, and not breaching the Other Party's contractual obligations related to their licence agreement and intellectual property law.
- This means that the Parties should further clarify the position of the Claimant's substance in the context of the intellectual property rights and contractual obligations related to the patent for which the Other Party holds a licence. It means further that the Claimant needs to find a way to reassure the Other Party that data-sharing and consequent registration and potential start of import by the Claimant will not result in a breach of the Other Party's contractual obligations under the licensee agreement. The Other Party has a legitimate interest to ensure that concluding a data-sharing agreement with the Claimant does not lead to such an infringement. It is both Parties' obligation to make every effort to reach an agreement on data-sharing and joint submission that does not – intentionally or unintentionally – result in one of the Parties breaching their legal obligations.
- The Other Party has proposed several solutions to the Claimant. As the Claimant rejected all of these, they should try to follow one of the proposals of the Other Party, or should find a new alternative solution, in order to fulfil both above-mentioned objectives. Both Parties need to make every effort to find a pragmatic solution in this respect; if the proposals made by the Other Party are not acceptable to the Claimant, the Claimant could e.g. make alternative proposals to the same effect.
- In case the Parties reach an agreement on how to address the Other Party's concern, the Parties should engage in negotiations on sharing of the information in the Other Party's dossier. This includes making every effort to agree on sharing the relevant information and incurred costs in a fair, transparent and non-discriminatory way.
- Registrants and potential registrants with the same substance are obliged to register as part of the same joint submission. This obligation pursuant to Article 11 of REACH is without prejudice to the fact whether the Parties share information or not.

³³ 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.

"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."