23 March 2018
PRIVILEGED & CONFIDENTIAL

CASE T-545/11 RENV *STICHTING GREENPEACE NEDERLAND AND PAN EUROPE V COMMISSION*

ORAL STATEMENT
ON BEHALF OF CLA AND NAM

Mr. President, honoured Members of the Court,

1. I appear before you today to support the European Commission in this important case. I fully agree with the legal position as set out on behalf of the Commission.

2. My focus today will be two-fold: (i) the importance of this case not just in Europe, but globally, and (ii) the EU's international law obligations.

3. My clients' involvement in these proceedings is evidence in itself of the crucial impact this case will have on international markets.

   My clients represent over 10,000 US-based companies which each year submit hundreds[1] of applications for the marketing and use of their products in the EU. As part of such applications, they are required to provide highly confidential information. Member companies provide this information to regulators on the premise that the proprietary data is safeguarded from unnecessary disclosure.

4. If there are no such **safeguards,** the ability of global companies to continue marketing their products in the EU will be at risk.

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[1] An Overview Report on a series of audits carried out in EU Member States in 2016 and 2017 evaluating the systems in place for the authorization of plant protection products, published by DG Health and Safety on 18 July 2017, shows the number of applications received for evaluation in 2013 and 2014 to some of the rapporteur Member States: (i) 248 application received by France; (ii) 140 applications received by Germany; and (iii) 199 applications received by the United Kingdom.

5. It takes at least 10 years and costs several hundred million to bring a new plant protection active ingredient to market in the EU.[2] There is no doubt that companies may decide not to enter EU markets if such entry would put their investments and proprietary product composition and manufacturing data at risk.

6. The effects of disclosure will not be limited to Europe. Once the data is disclosed, it can be used for competitive purposes anywhere in the world. In the US for example, disclosure of the three types of data at issue in this case would lead to loss of trade secret protection – putting many millions of dollars of R&D investment at risk – and also to loss of data compensation rights if competitors rely on the data in getting product registrations with the EPA.

7. Disclosure in this case would also put important EU policy objectives at risk. The Europe 2020 Strategy identifies innovation as "*the overarching policy objective*".[3] Innovation is critical for the EU economy to thrive and also to bring sustainable and safe products to market. The Commission confirmed in its recent *Dow/DuPont* merger decision that "*[i]nnovation is crucial to deliver products which meet the more stringent [regulatory] criteria and replace older technology*" (para. 1980); and "*[f]rom a general public policy perspective, new AIs can also ensure reduced toxicity…*" (para. 1977). The *Bayer/Monsanto* decision, announced just two days ago, reiterates – once again – the importance of these objectives.

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2 *See* ECPA, Statement in Intervention in Case C-673/13 P: '*[a]t least 10 years and more than EUR 230 million are needed to bring a new PPP substance on the EU market. The development cost, which is mainly the cost of conducting new studies, has risen significantly over the years to nearly 60% (around EUR 133 million) of the overall cost of getting a substance from research to approval stage*'.

3 The Europe 2020 Strategy is the EU's plan for "*growth and jobs from 2010 and 2020*". It consists of seven flagship initiatives, including the "Innovation Union". The Communication from the Commission (link here) states that: "*the biggest challenge for the EU and its Member States is to adopt a much more strategic approach to innovation. An approach whereby innovation is the overarching policy objective, where we take a medium- to longer term perspective, where all policy instruments, measures and funding are designed to contribute to innovation*".

8. I will now move on to the second part of my statement. I will explain why the EU's international obligations mandate that the Court must uphold the Commission's decision in this case.

9. The Commission is bound to interpret the various disclosure rules relevant to this case – *as far as possible* – in line with the EU's international obligations under the WTO TRIPS Agreement. The Commission is also bound to respect the fundamental right to property – including trade secrets and IP – guaranteed by the EU Charter and the ECHR.

10. In particular, Article 39(3) of the TRIPS Agreement concerns data that must be submitted to obtain marketing approval of agricultural chemical products. It **requires that the EU protect such data against disclosure, except where (i) *necessary to protect the public*, or (ii) unless steps are taken to ensure that the data are protected against unfair commercial use**.

11. All these rules have in common that the EU must weigh the commercial interest in protecting the data at issue against a public interest of disclosure.[4][5] In this case, disclosure must be ***necessary*** in the public interest to protect the environment.

12. This weighing exercise must allow for effective protection of commercial interests. The Court of Justice set aside the General Court's judgment in this case because an overbroad interpretation of the concept of '*information*

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4 For example, in relation to Article 4(2) of the Transparency Regulation, EU Courts repeated on several occasions, that "*the system of exceptions laid down in Article 4 of Regulation No 1049/2001, and particularly in Article 4(2), is based on a weighing of the opposing interests in a given situation*,"[4] Therefore, "*[t]he decision taken on a request for access to documents depends on what interest must prevail in the particular case*." See, e.g., Case C-514/11 P and C-605/11 P, *LPN and Finland v Commission*, EU:C:2013:738, para. 42; Case T-451/15, *AlzChem AG v Commission*, ECLI:EU:T:2017:588, para. 66; Case T-189/14, *Deza v ECHA*, ECLI:EU:T:2017:4, para. 53; Case T-245/11, *ClientEarth and International Chemical Secretariat v ECHA*, EU:T:2015:675, para. 168.

5 *See* para. 81 of the Court of Justice judgment, where the Court said that, in accordance with first indent of Article 4(2) of Regulation No 1049/2001, '*the institutions [should be allowed] to refuse to disclose environmental information on the ground (…) that such disclosure would have an adverse effect on the protection of the commercial interests*'.

on emissions' would not have allowed for effective protection of trade secrets and would thus be unlawful.[6]

13. Determining whether disclosure is ***necessary*** to protect the public requires a careful case-by-case assessment of the relevant information. That assessment was undertaken in this case by the Commission. [And I note that the Court's review is limited to checking for *manifest error* or *misuse of powers* in that assessment – the Court should refrain from substituting its own assessment in matters, such as this one, involving complex scientific and technical considerations.]

14. [As the Commission and several interveners have explained this morning], disclosure in this case was **not necessary** and **does not contribute** to the policy objective aimed at preserving, protecting and improving the quality of the environment.

This is because:

- The data at issue does not concern products that will actually (or foreseeably) be released into the environment. The data at issue will not allow the public to understand what is released into the environment under normal or realistic conditions of use for which marketing authorisation was granted and which prevail in the area where the product is used [I am referring here to the test in para. 79 of the judgment of the Court of Justice in Case 673/13].

- The data that is relevant to environmental and health effects has already been disclosed as mandated by Article 63(2) of the Plant Protection Products Regulation 1107/2009.

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6 *Ibid*., para. 81, "*that concept [i.e., "information [which] relates to emissions" may not (…) include information containing any kind of link, even direct, to emissions into the environment*". (…) *Such an interpretation would deprive of any practical possibility, laid down in the first indent of Article 4(2) of Regulation No 1049.2001, for the institutions to refuse to disclose environmental information on the ground, inter alia, that such disclosure would have an adverse effect on the protection of the commercial interests of a particular natural or legal person and would jeopardise the balance which the EU legislature intended to maintain between the objective of transparency and the protection of those interests.*"

15. The Commission's interpretation is in line with TRIPS and fundamental rights obligations because it limits disclosure to data about actual emissions that affect the environment, and whose disclosure thus contributes to public policy objective.

16. The Commission's interpretation also upholds the very clear position set out by the EU legislator in Article 63(2) of the Plant Protection Products Regulation. As noted by AG Kokott, the information at issue in this case falls squarely within the types of data identified in that provision as benefitting from confidentiality. The Regulation post-dates the Aarhus rules so the legislator was well aware of transparency obligations – including the *emissions rule* – when it adopted Regulation 1107/2009. In the words of AG Kokott (para. 57 Opinion): *"the view cannot be taken that the legislature intended to adopt a provision which was ineffective in practice."*[7]

17. In conclusion, the Commission's interpretation of the *emissions rule* is consistent with the EU's international obligations; the Applicants' interpretation is not. **The Court must therefore favor the Commission's interpretation and uphold the Commission's decision in this case.**

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THANK YOU!

[7] Joined Cases C-453/03, C-11/04, C-12/04 and C-194/04, *ABNA and Others*, EU:C:2005:741, paras. 82 and 83. This case was also mentioned in the Opinion of Advocate General Kokott, at para. 59, where she said: "*This reassessment found in particular that information on the full composition of the plant protection product and on residues in the active substance should be protected. As the Commission explained in connection with the refusal of access, such information is sensitive above all because it makes it easier for conclusions to be drawn regarding the production process and thus for copying to take place. Consequently, this reassessment by the legislature is consistent with the appraisal by the Court in ABNA and Others.*"