An Arbitration under the Agreement of 14 February 1989 between the Government of the French Republic and the Government of the Polish People's Republic Concerning the Mutual Promotion and Protection of Investments

Les Laboratoires Servier, S.A.S.
Biofarma, S.A.S.
Arts et Techniques du Progrès S.A.S.

v.

Republic of Poland

FINAL AWARD

Tribunal

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The Honourable Marc Lalonde
Professor William W. Park, Presiding Arbitrator

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Registry

Permanent Court of Arbitration

CONTENTS

I. THE PARTIES AND THEIR REPRESENTATIVES

1. The Claimants in this matter are Les Laboratoires Servier S.A.S. ("Laboratoires"), Biofarma S.A.S. ("Biofarma"), and Arts et Techniques du Progrès S.A.S. ("Arts et Techniques", collectively "Servier" or "Claimants"), pharmaceutical companies constituted under the laws of France. The Claimants are represented by Mr. Barton Legum and Ms. Anna Crevon of SCP Salans & Associés, 5 boulevard Malesherbes, 75008 Paris, France, and Mr. Wojciech Kozlowski, Salans D. Oleszchuk Kancelaria Prawnicza sp. K, Rondo ONZ 1, 00-124 Warsaw, Poland.

2. The Respondent is the Republic of Poland ("Respondent" or "Poland"), represented by Ms. Judith Gill QC, and Messrs. Jeffrey Sullivan and Thomas Sebastian of Allen & Overy LLP, One Bishops Square, London E1 6AD, England; Mr. Wojciech Jaworski of Allen & Overy, A. Pędzich sp. K., Rondo ONZ 1, 34 floor, 00-124 Warsaw, Poland; and Mmes. Barbara Kotlarek-Kmin, Elżbieta Buczkowska-Krzyśków, and Katarzyna Szostak-Tebbens from the Prokuratoria Generalna Skarbu Państwa, State Treasury Solicitor's Office, Ul. Hoża 76/78, 00-682 Warsaw, Poland.

II. PROCEDURAL HISTORY

3. The Tribunal incorporates by reference the procedural history set forth in paragraphs 3 to 13 of the Interim Award on Jurisdiction dated 3 December 2010.

4. By a Notice of Arbitration dated 30 October 2009, the Claimants commenced arbitration against Poland pursuant to Article 8 of the Treaty on the Mutual Encouragement and Protection of Investments between France and Poland, signed on 14 February 1989, which entered into force on 10 February 1990 ("Treaty" or "BIT") and Article 3 of the UNCITRAL Arbitration Rules 1976 ("UNCITRAL Rules").

5. Article 8 of the Treaty provides:

> 1. Any dispute relating to investments between one Contracting Party and an investor of the other Contracting Party shall, as far as possible, be settled amicably between the two parties concerned or, failing that, through internal means of recourse.
>
> 2. However, disputes relating to the divestment measures referred to in article 5, paragraph 2, particularly those relating to possible compensation, its amount and terms of payment and the interest payable in the event of a delay in payment, shall be settled according to the following conditions:
>
> If any such dispute has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute, it shall, at the request of either party, be submitted to arbitration. It shall be settled definitively in accordance with the Arbitration Rules of the United Nations

Commission on International Trade Law, as adopted by the General Assembly of the United Nations in resolution 31/98 of 15 December 1976.

When both Contracting Parties have become parties to the Convention on the settlement of investment disputes between States and nationals of other States, signed at Washington on 18 March 1965, any such dispute which has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute shall be submitted for arbitration to the International Centre for Settlement of Investment Disputes.

3. The arbitral tribunal shall rule in accordance with the provisions of this Agreement and the rules and principles of international law.

6. On 20 May 2010, the Claimants filed a Statement of Claim ("Statement of Claim"), in which they contended, *inter alia*, that (1) they have been dispossessed of their investment in violation of Article 5(2) of the Treaty; and (2) Poland has breached Articles 3, 4(1) and 5(1) of the Treaty, including the guarantee of fair and equitable treatment; non-arbitrary and non-discriminatory treatment; national treatment; and full protection and security ("Non-Expropriation Claims"). The Claimants argued that, by virtue of the MFN clause in Article 4(1) of the Treaty and the wider dispute resolution provisions contained in Article 8 of the Poland-Finland BIT, this Tribunal has jurisdiction to resolve their Non-Expropriation Claims (the "MFN Issue").

7. On 31 May 2010, the Claimants filed a corrected version of the Statement of Claim, a corrected translation of Exhibit C-18, and a corrected version of Exhibit C-106, the Witness Statement o[redacted]

8. On 21 June 2010, Poland raised preliminary objections to the Claimants' claims, including that: (1) the Claimants do not have a protected investment relevant to their claim under Article 5(2) of the Treaty; and, (2) the Tribunal does not have jurisdiction to resolve the Claimants' Non-Expropriation Claims by virtue of the MFN clause in Article 4(1) of the Treaty. Poland sought bifurcation of the proceedings in relation to those objections, to which the Claimants objected.

9. On 16 July 2010, the Respondent filed a request for the production of documents. On 30 July 2010, the Claimants filed their response to this request. On 17 August 2010, the Tribunal issued its decision on this document production dispute.

10. By letter dated 20 July 2010, Poland submitted that the Claimants were also seeking to assert a further and separate basis for the Tribunal's jurisdiction pursuant to the applicable law clause found at Article 8(3) of the Treaty. Poland requested that this issue also be dealt with in a preliminary phase. By letter dated 28 July 2010, the Claimants objected to Poland's qualification of their position on Article 8(3) of the Treaty, and the bifurcation of this issue. The Parties exchanged further correspondence on this matter on 29 July and 2 August 2010.

11. On 3 August 2010, the Tribunal communicated its preliminary decision to bifurcate the proceedings to address, as a first matter, the MFN Issue. On 27 August 2010, the Tribunal issued a full Decision on Poland's Application for Bifurcation of the Proceedings, in which it confirmed its decision to bifurcate the proceedings with respect to the MFN Issue only.

12. Between August and October 2010, the Parties submitted pleadings on the MFN Issue. A hearing was held on 8 October 2010. As memorialised in the provisional timetable of 27 August 2010, the Parties agreed that the Tribunal would communicate its decision on the MFN issue to the Parties as soon as practicable after the hearing to facilitate the Parties' forthcoming submissions, with a reasoned award to follow. On 14 October 2010, the Presiding Arbitrator notified the Parties of the Tribunal's decision as follows:

> Having fully considered the Parties' written submissions and oral arguments presented in connection with Respondent's jurisdictional objections, the Tribunal is unanimously of the view that its jurisdiction has not been expanded by virtue of the MFN provisions in Article 4(1) of the Franco-Polish Investment Treaty signed on 14 February 1989.
>
> As requested by both sides, and pursuant to the Decision on Bifurcation and Provisional Timetable of 27 August 2010, the Tribunal provides this notification of its decision for the Parties' guidance. A reasoned award on the matter will follow as soon as possible, with the target date of 3 December 2010 set in the Provisional Timetable.
>
> As provided in Section 3 of the Decision on Bifurcation, any arguments concerning applicable law, including the effect of Article 8(3) of the Investment Treaty, will be addressed in the context of the merits phase of this case as to which hearings have been fixed for July 2011.

13. On 3 December 2010, the Tribunal issued its reasoned Interim Award on Jurisdiction to the same effect as its written notification to the Parties of 14 October.[1]

14. Following an exchange of correspondence between the Parties, on 19 November 2010, Poland requested an order that the Claimants produce the auditor's notes to the financial accounts of Servier's Polish subsidiaries from 2006 to 2009, to which the Claimants objected. In a decision dated 27 November 2010, the Tribunal declined to order production of the auditor's notes.

15. On 25 October 2010, the Claimants filed a request for production of documents. On 6 December 2010, the Respondent filed its response to the Claimants' request. In keeping with the provisional timetable, Servier filed a supplementary request for document production on 7 January 2011, to which Poland responded on 28 January 2011. By letter dated 8 February 2011, Servier submitted the unresolved document production issues to the Tribunal for determination, and Poland submitted its comments thereon on 9 February 2011.

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[1] Interim Award on Jurisdiction, paras. 121-122. For the full procedural history leading up to the rendering of the Interim Award on Jurisdiction, *see* paras. 16-23 therein.

16. On 2 February 2011, the Claimants requested the Tribunal to rule that partially redacted meeting minutes submitted by Poland under Exhibits R-90 and R-104 were not protected by legal privilege and should be fully disclosed. Poland objected to this request on 9 February 2011.

17. After allowing the Parties further opportunity to comment, in a decision dated 22 February 2011, the Tribunal ruled on (1) the Parties' outstanding document production issues; and (2) the Parties' dispute concerning Exhibits R-90 and R-104. Following further disagreement between the Parties concerning the Respondent's redaction of documents responsive to Servier's request of 7 January 2011, on 23 March 2011, the Tribunal issued further directions as to the extent to which such documents could be redacted.

18. On 23 December 2010, the Respondent filed its Objections to Jurisdiction and Statement of Defence ("Statement of Defence").

19. On 29 March 2011, the Claimants filed their Reply Memorial ("Reply"). In it, they requested the Tribunal to exclude from the record of this arbitration: (1) Exhibits R-130 through R-144 inclusive; (2) the witness statement of Dr. Nopitsch-Mai; (3) Section 7 (paras. 71-91) of the witness statement of Professor Mazurek; and (4) those portions of Poland's Statement of Defence which expressly rely on the above-mentioned documents.

20. On 30 May 2011, the Claimants filed their Supplement to Claimants' Reply Memorial as agreed by the Parties on 19 May 2011 ("Supplement"). The Supplement addressed the Respondent's supplemental disclosure of documents made on 12 April 2011, in response to the Tribunal's document production orders of 22 February and 23 March 2011.

21. On 10 June 2011, the Respondent filed its Rejoinder Memorial ("Rejoinder"). At paragraph 438 of its Rejoinder, Poland requested the Tribunal to reject Servier's request noted above in paragraph 20.

22. On 21 June 2011, the Tribunal held a pre-hearing telephone conference call with the Parties. On 24 June 2011, the Tribunal issued Hearing Protocols.

23. On 20 June 2011, the Claimants informed the Tribunal that Dr [redacted] would be unable to attend the hearing due to a conflicting inspection. On 23 June 2011, the Respondent complained that the Claimants could have provided earlier notice of Dr. [redacted]s unavailability, and had control over the scheduling of the conflicting inspection. Thus, the Respondent filed an application to disregard the written witness statement of Dr. [redacted] because he would not be able to be cross-examined at the hearing. On the same date, the Claimants retorted that they had had no control over the scheduling of the inspection.

24. On 30 June 2011, the Tribunal informed the Parties that the Tribunal would reserve judgment on what weight, if any, to accord to Dr. [redacted]s written statement.

25. Having duly considered the matter, the Tribunal declines to reject the testimony of Dr. [redacted] but grants it only such weight as deserved under the circumstances.

26. From 4 to 8 July 2011, the Tribunal held a hearing at the PCA's facilities in the Peace Palace in The Hague, the Netherlands.

27. On 11 July 2011, the Respondent filed an updated Application to Exclude, in which it requested the exclusion of new arguments asserted by the Claimants for the first time at the hearing on 8 July 2011, citing the instructions issued by the Tribunal during the hearing.

28. On 15 July 2011, the Claimants submitted their response to the Respondent's Application to Exclude.

29. On 20 July 2011, the Tribunal issued its Procedural Order on Post-Hearing Procedural Items. The Tribunal invited the Parties to submit post-hearing briefs providing a summary of each side's position, including rebuttal of any arguments presented during the hearing. Initial post-hearing submissions, up to 18,200 words each, were to be filed simultaneously by 29 July 2011. The second post-hearing submissions were to be filed by 19 August 2011, limited to 9,100 words each and to observations and arguments responsive to matters raised in the first post-hearing round. The Tribunal also ruled that the Parties could comment on the principles to be applied in determining the reasonableness of requests for costs in two rounds of submissions. The first submissions on costs would be limited to 4,500 words and due on 20 September 2011, while the second submissions on costs would be limited to 2,250 words and due on 30 September 2011. The Tribunal further decided that either side could require documents referenced in an expert report to be available as part of the record. Finally, the Tribunal declined to grant the Respondent's Application to Exclude the Claimants' arguments with respect to Article 24 of the EU Pharmaceutical Directive and the alleged investment in Poland by Laboratoires, and directed that the Parties address both matters in their post-hearing submissions.

30. On 27 July 2011, the Tribunal granted the Parties' joint request for extension of the deadline for filing post-hearing briefs to 31 July 2011.

31. On 31 July 2011, the Parties filed their first post-hearing submissions.

32. On 19 August 2011, the Parties filed their second post-hearing submissions.

33. On 20 September 2011, the Parties filed their first submissions on costs.

34. On 30 September 2011, the Parties filed their second submissions on costs.

III. RELEVANT TREATY PROVISIONS

35. The Preamble of the Treaty provides:

> The Government of the French Republic and the Government of the Polish People's Republic, hereinafter referred to as "the Contracting Parties",
>
> Desiring to strengthen economic cooperation between the two States and to create favourable conditions for French investments in Poland and Polish investments in France,
>
> Convinced that the promotion and protection of such investments are likely to stimulate transfers of capital and technology between the two countries in the interest of their economic development, [...].

36. Article 4 of the Treaty provides:

> 1. Each Contracting Party shall accord in its territory and maritime areas to investors of the other Party, in respect of their investments and activities connected with such investments, the same treatment as is accorded to its own investors or the treatment accorded to investors of the most favoured nation if the latter is more advantageous.
>
> 2. Such treatment shall not, however, include privileges which a Contracting Party extends to the investors of a third State by virtue of its participation in or association with a free trade area, customs union, common market or any other form of regional organization or organization for mutual economic assistance.
>
> 3. This Agreement shall not include privileges extended by a Contracting Party to any third State by virtue of an agreement for the avoidance of double taxation or any other agreement with respect to taxes.

37. Article 5 of the Treaty states:

> 1. Investments made by investors of one Contracting Party shall be fully and completely protected and safeguarded in the territory and maritime areas of the other Contracting Party.
>
> 2. The Contracting Parties shall not take any expropriation or nationalization measures or any other measures which would have the effect of divesting investors of the other Party, either directly or indirectly, of investments belonging to them in its territory or maritime areas, except for reasons of public necessity and on condition that these measures are not discriminatory or contrary to a specific undertaking.
>
> Any divestment measures that may be taken shall give rise to the payment of prompt and adequate compensation, the amount of which shall correspond to the real value of the investments in question on the day before the measures are taken or made known to the public.
>
> Such compensation, its amount and its method of payment shall be determined no later than the date of divestment. The compensation shall be effectively realizable, paid without delay and freely transferable. It shall yield, up to the date of payment, interest calculated on the basis of the appropriate rate of interest in force at the time of divestment.
>
> 3. Investors of either Contracting Party whose investments have suffered losses as a result of war or any other armed conflict, revolution, state of national emergency or uprising in the territory or maritime areas of the other Contracting Party shall be accorded by the latter Party treatment no less favorable than that accorded to its own investors or to investors of the most favoured nation. They shall in any event receive adequate compensation.

38. Article 8 of the Treaty provides:

> 1. Any dispute relating to investments between one Contracting Party and an investor of the other Contracting Party shall, as far as possible, be settled amicably between the two parties concerned or, failing that, through internal means of recourse.
>
> 2. However, disputes relating to the divestment measures referred to in article 5, paragraph 2, particularly those relating to possible compensation, its amount and terms of payment and the interest payable in the event of a delay in payment, shall be settled according to the following conditions:
>
> If any such dispute has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute, it shall, at the request of either party, be submitted to arbitration. It shall be settled definitively in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law, as adopted by the General Assembly of the United Nations in resolution 31/98 of 15 December 1976.
>
> When both Contracting Parties have become parties to the Convention on the settlement of investment disputes between States and nationals of other States, signed at Washington on 18 March 1965, any such dispute which has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute shall be submitted for arbitration to the International Centre for Settlement of Investment Disputes.
>
> 3. The arbitral tribunal shall rule in accordance with the provisions of this Agreement and the rules and principles of international law.

IV. FACTUAL BACKGROUND

A. POLAND'S REGULATORY REGIME AND HARMONISATION OF PHARMACEUTICAL PRODUCTS

1. Applicable laws and regulations

39. Starting in 1991, Poland enacted a series of legislative and administrative reforms to harmonise its regulation of pharmaceuticals with that of the European Union (then called the European Communities). Thus, under the 1991 Europe Agreement between Poland and the European Communities,[2] Poland was required to approximate its "existing and future legislation to that of the Community," while the Polish legislature was obliged to "use its best endeavours to ensure that future legislation is compatible with Community legislation," including the "protection of health and life of humans." At that time, Polish pharmaceutical law was governed mainly by the 1991 Act on Pharmaceuticals, Medical Materials, Pharmacies, Wholesale Warehouses and Pharmaceutical Inspection ("1991 Pharmaceutical Act").

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[2] The 1991 Europe Agreement established an association between the European Communities and their Member States, on the one hand, and the Republic of Poland, on the other. *See* Statement of Defence, para. 48.

40. Prior to its accession to the European Union in 2004, and in anticipation of the EU's Pharmaceuticals Directive,[3] Poland proceeded to enact legislation in accordance with its obligations under the Europe Agreement. Thus, on 6 September 2001, Poland adopted the Pharmaceutical Law and the Act on Introductory Provisions of the Pharmaceutical Law ("Act on Introductory Provisions"). The Pharmaceutical Law and the Act on Introductory Provisions entered into force on 1 October 2002, and together they represent the main sources of regulation of pharmaceutical products in Poland.

41. Ancillary to those two statutes is the Act on the Office for the Registration of Medicinal Products, Medical Devices and Biocidal Products dated 27 July 2001 ("Registration Office Act"), which created the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products ("Registration Office"). The Registration Office has broad administrative discretion in the areas of pharmaceutical approval and regulation.

42. Under the 1991 Pharmaceutical Act, a drug could be sold in Poland only after the issuance of a Resolution by the Registration Committee, which resulted in the drug's entry into the Register of Medicinal Products ("Register"). Similarly, pursuant to the EU-compliant Pharmaceutical Law, the seller of a drug in Poland must possess a marketing authorisation for that drug, issued either by the competent Polish authorities or by the European Commission. Depending on the issuing authority and issuance procedure, the marketing authorisation can be valid either in Poland specifically or in the European Union as a whole. Failure to procure a marketing authorisation for a drug on the Polish market entails regulatory and other sanctions under Polish law.

43. There is disagreement between the Parties as to whether the Pharmaceutical Law introduced "more stringent" requirements than the 1991 Pharmaceutical Act that it replaced. The Respondent argues that the EU-imposed requirements introduced a stricter regulatory regime,[4] and points out that Servier itself referred to the "more stringent" requirements of the Pharmaceutical Law and the Act on Introductory Provisions.

44. At this point it is worth recounting the various procedures by which a seller of a pharmaceutical in Poland can procure a marketing authorisation. Broadly speaking, there are four such procedures, one of which is "national," *i.e.*, governed by Polish law, and three additional ones that are governed by EU law.

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[3] Exhibit C-82, Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001).

[4] *See, e.g.*, Statement of Defence, para. 85.

45. The national procedure in Poland consists of the submission of a request for a marketing authorisation, accompanied by the necessary documentation, to the Minister of Health through the Registration Office. Under the Pharmaceutical Law, the required documentation includes

> ...detailed quantitative and qualitative particulars of the active substance or active substances and other substances, referring to the medicinal product, and their usual common names [*i.e.* the International non-proprietary names (INN) recommended by the WHO] and if such names do not exist their chemical names;
>
> ...
>
> results, summaries, and reports for:
> a) pharmaceutical, i.e. physicochemical, biological or microbiological, studies,
> b) preclinical, i.e. pharmacological and toxicological, studies,
> c) clinical trials....

After reviewing the request and associated documentation, the Registration Office is responsible for preparing a report thereon for the Minister's review. If the Minister grants the request, the marketing authorisation is valid for five years.

46. The Polish Pharmaceutical Law also contains provisions mandating the denial of an application for a marketing authorisation. Specifically, under Article 30(1) of that law:

> The minister competent for health matters shall issue the decision refusing to grant the authorisation if:
>
> 1) the application and the dossier submitted in support of the application do not comply with the requirements laid down in the Act;
>
> 2) the results of tests and studies demonstrate that the medicinal product is characterised by risk of use unbalanced by the expected therapeutic effect within the framework of the indications, contraindications and prescribed dosing stated in the application;
>
> 3) the results of tests and studies demonstrate that the medicinal product does not have the declared therapeutic efficacy or the therapeutic efficacy is insufficient;
>
> 4) the results of tests and studies demonstrate that the qualitative or quantitative composition or another qualitative characteristic of the product is not as declared;
>
> 5) the withdrawal period specified by the MAH is not long enough to ensure that the foodstuffs derived from the treated animals do not contain products posing a potential risk to human health or such period is not sufficiently evidenced.

[redacted]

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[5] Reply, para. 34.

[redacted]

48. According to Poland, Servier's argument relies on a false factual premise.[8] Poland's decisions not to renew the marketing authorisations for Detralex and Eurespal Syrup were grounded explicitly on [redacted][9] The Respondent does not dispute that neither application sought a new marketing authorisation, or that its decisions with respect to harmonisation applications were not permitted to be grounded in [redacted] However, Poland denies that harmonisation applications were governed by a lesser standard than new applications, or were subject to a less stringent evaluation. Rather, following a full review of the dossiers for each drug, Poland was required to satisfy itself that the registrations for Detralex and Eurespal Syrup complied with the standards of quality, safety, and efficacy under the *acquis*. Its decisions with respect to each drug were based on [redacted][10]

49. Aside from the Poland-specific national procedure, there are three types of EU law-based authorisation procedures: "centralised," "decentralised," and "mutual recognition." The centralised procedure is governed by EU Regulation 726/2004, and involves obtaining a marketing authorisation directly from the European Commission or, in rare instances, from the Council of the European Union on the basis of a recommendation by the European Medicines Agency ("EMA"). Such an authorisation is valid in all EU Member States and in the European Free Trade Association ("EFTA," *i.e.*, Iceland, Liechtenstein, Norway and Switzerland). Only certain categories of drugs are eligible for this procedure. Neither Detralex nor Eurespal Syrup, the medicines at issue in this case, is eligible for marketing authorisation via the centralised procedure.

50. The decentralised procedure, which involves simultaneous applications to the European authorities and the Polish Ministry of Health, is similarly inapplicable to Detralex and

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6 Reply, paras. 31, 38; Claimants' First Post-Hearing Submission, paras. 21-30.

7 Claimants' First Post-Hearing Submission, para. 23.

8 Rejoinder, para. 25.

9 Rejoinder, para. 20.

10 Respondent's First Post-Hearing Brief, paras. 40-42.

Eurespal Syrup because it concerns only new requests for marketing authorisation, and not renewal applications.

51. Finally, the mutual recognition procedure applies when marketing authorisation is sought in Poland, which is called the "concerned Member State," for a drug that already has received such authorisation in another EU or EFTA Member State, the "reference Member State." The applicant must notify both the concerned and the reference Member States of its application. Within 90 days of that notification the reference Member State must supply the concerned Member State with an assessment report as to the pharmaceutical in question. The applicant, meanwhile, must supply all information required under the centralised procedure in addition to a declaration of consistency of its documentation with that provided by the reference Member State. After receiving these materials, the concerned Member State is obliged to recognise the marketing authorisation granted by the reference Member State within 90 days unless "reasonable concerns arise that marketing authorisation of the medicinal product concerned might pose a risk to public health." If the concerned Member State harbours such concerns, it is required to submit them in detail to a group of representatives or all Member States. If those representatives fail to reach a resolution within 60 days, the matter is referred to the EMA and the European Commission for binding settlement.

52. All four of the above marketing authorisation procedures require complete documentation with respect to the pharmaceutical concerned. The extent of such documentation, however, can vary depending on whether the application concerns an original drug, a generic drug, or a drug with "well-established use." Thus, while the European Pharmaceutical Directive requires a full scientific dossier for an original drug, including clinical trial data, that requirement is dispensed with if the drug is a "generic" of a medicinal product already authorised. Similarly, a full scientific dossier is not required if the active substance or substances in the pharmaceutical has been in systematic and documented use for at least ten years, and is of recognised efficacy and acceptable safety level.

53. As mentioned, the substantive evaluation of market authorisation applications in Poland is conducted, as an initial matter, by the Registration Office. That office prepares and submits a report on each application to the Minister of Health, who has the power to approve or deny the application. The Registration Office's evaluation proceeds in seven stages, some of which may be completed simultaneously: i) formal verification or validation of the application; ii) quality assessment (chemical, pharmaceutical, and biological documentation); iii) safety assessment (Periodic Safety Assessment Report and clinical report thereon); iv) safety/efficacy assessment (toxicological and pharmacological

documentation); v) safety/efficacy assessment (clinical documentation); vi) evaluations of product information, including the Summary of Product Characteristics, package leaflet and labels for packaging; and vii) preparation of the report of the President of the Registration Office for the Minister of Health.

54. There are two noteworthy aspects of the Registration Office review process. First, under the Act on Introductory Provisions, a decision on a marketing authorisation application, including a renewal application, must be taken within six months. If, however, the Minister of Health is unable to make a determination on a renewal within this time period, the marketing authorisation can be extended for twelve months. Similarly, if a marketing authorisation holder submits an incomplete renewal application under the Pharmaceutical Law, the duration of its authorisation may be prolonged to allow it to submit the missing documentation. In any event, the Registration Office is not required to process incomplete applications.

55. Second, while the Registration Office employs teams of specialized scientists, it may involve external independent experts to assess a portion of a scientific dossier submitted with an application. Both internal and external expert teams must prepare protocols with positive and negative assessments of the materials they have reviewed, which assessments are then taken into account in preparing the report of the President of the Registration Office to the Minister of Health.

56. The Minister of Health conducts an independent review of the report of the Registration Office and has discretion to make a decision contrary to the Office's assessment. As mentioned, the Minister's discretion is limited by the mandatory grounds for rejection of an application under [redacted] Furthermore, the Minister may not amend or approve partially an application. Finally, if the Minister denies an application, the applicant can request reconsideration, which the Minister performs with the assistance of the Registration Office. If the negative assessment stands, the applicant can resort to the Voivodship Administrative Court.

2. Poland's harmonisation process for previously authorised pharmaceuticals

57. Poland's accession to the EU on 1 May 2004 occurred subject to certain conditions contained in the Act of Accession, which was annexed to the Treaty of Accession. Article 24 of the Act of Accession referred to transitional arrangements that would apply to the newly acceded Member States. Annex XII, which applied specifically to Poland, contained a list of pharmaceutical products that had received marketing authorisation without concomitant compliance with EU law. According to the Annex, marketing authorisations

for those products would remain valid in Poland until the Polish authorities could evaluate them anew under EU law, or until 31 December 2008, whichever occurred earlier, without any prejudgment as to their compliance with EU law requirements.[11]

58. Notably, the Act and Treaty of Accession did not specify a framework for the re-evaluation under EU standards of the pharmaceuticals listed in Annex XII of the Act of Accession. Discretion was thus provided to the Member States to establish their own internal procedures for such re-evaluation. Poland's methodology was to treat the re-evaluation as a market authorisation renewal governed by Articles 29 and 30 of the Pharmaceutical Law, as modified by Article 14 of the Act on Introductory Provisions. In other words, Poland's authorities elected to conduct a full review of the dossiers of the drugs appearing in Annex XII of the Accession Act.[12]

59. The Parties accept that the Act of Accession required Servier to "harmonise" the marketing authorisations for its drugs sold in Poland by supplying Poland with additional evidence for those drugs. The Parties disagree, however, as to [redacted]

[11] Statement of Defence, paras. 77-80.

[12] According to the Respondent, this review process involved 7,349 products listed in Annex XII, of which 6,771 were harmonised, including 12 of Servier's drugs, while 401 were withdrawn, and 177, including Detralex and Eurespal Syrup, were rejected. Statement of Defence para. 84; Respondent's First Post-Hearing Brief, para. 40.

[13] Reply, para. 45.

[14] Servier's Letter to the Tribunal of 15 July 2011, p. 2; Reply, paras. 42-45.

[15] Rejoinder, para. 26.

[16] Respondent's First Post-Hearing Brief, paras. 72-73.

[redacted]

61. Similarly, the Parties dispute what legal framework is applicable to the "harmonisation" of Servier's pharmaceuticals. According to Servier, the Polish Office of Registration stated that it would apply "the laws in force as of the accession day, that is, 1 May 2004."[18] Servier interprets this statement as referring only to the laws in force on 1 May 2004, and not beyond that date. Poland denies that laws adopted subsequent to that date were not relevant to the review and harmonisation process.

[redacted]

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17 Respondent's First Post-Hearing Brief, paras. 70-71 (emphasis in the original).

18 Reply, paras. 48-49 (quoting Exhibit C-29, Power Point presentation by Registration Office employee Dr. Sarna, at 2).

19 The Respondent notes that [redacted] Statement of Defence, para. 82.

20 Reply, para. 52; Claimants' First Post-Hearing Submission, para. 14.

21 Rejoinder, paras. 34-36, 40.

[redacted]

B. THE DETRALEX HARMONISATION PROCESS

1. The Detralex Harmonisation Application

66. Servier obtained the 1999 registration certificate (the equivalent of a marketing authorisation) for Detralex pursuant to the 1991 Pharmaceutical Act. This registration certificate was valid until 30 June 2004 [redacted]'. On 1 October 2002, Detralex's registration certificate of 27 May 1999

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[22] Reply, para. 54.

[23] Rejoinder, paras. 44-45.

automatically became a marketing authorisation ("1999 Marketing Authorisation") by operation of Article 14(1) of the Act on Introductory Provisions.[24]

67. Servier filed the Detralex Harmonisation Application to renew Detralex's 1999 marketing authorisation on 8 January 2004. The application specifies [redacted]

68. The 1999 Marketing Authorisation was prolonged twice during the harmonisation process in order to allow for the Detralex Harmonisation Application to be fully assessed and for necessary additional evidence to be filed by Servier. The first extension was made through Decision No. RR/1668/1633/04, extending the 1999 Marketing Authorisation until 30 June 2005. The second extension was made on 10 June 2005 through Decision No. RR/2377/05 which extended the validity of the 1999 Marketing Authorisation until 31 December 2008, the limit contemplated by the Act of Accession.[29]

[redacted]

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24 Statement of Defence, para. 92. [redacted]

25 Statement of Defence, para. 94.

26 Statement of Defence, para. 96; *cf.* Statement of Claim, para. 139.

27 Statement of Defence, para. 97 (citing Exhibit C-106, Witness Statement of [redacted].

28 Rejoinder, paras. 135-136.

29 Statement of Defence, para. 98.

30 Statement of Claim, paras. 122-123 (quoting the Law on Introductory Provisions Article 14(5a)).

[redacted]

[31] Statement of Defence, para. 102.

[32] Statement of Defence, para. 104 (quoting Exhibit R-44, Servier Letter 1006/513/RP/KC to the Registration Office dated 1 Aug. 2006).

[33] Statement of Defence, paras. 106-109.

[redacted]

[34] Statement of Defence, paras. 111-113.

[35] Statement of Defence, para. 113.

[36] Statement of Defence, para.114.

[37] Statement of Defence, para.113.

[38] Statement of Defence, para. 117 (citing Exhibit R-72, Servier Answers dated July 2007 to the Polish Questions of 16 April 2007).

[redacted]

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[39] Statement of Defence, paras. 120-122.

[40] Statement of Defence, para. 123.

[41] Statement of Defence, para. 135 (quoting Exhibit R-103, Registration Office letter PL/ZR-1942/08 to Servier dated 9 Sept. 2008).

[42] Statement of Claim, para. 127.

[43] Statement of Claim, para.128.

[redacted]

80. On 28 November 2008, the Registration Office reached a tentative decision not to renew the Detralex marketing authorisation. After Servier was allowed to present additional evidence, including a second Opinion by [redacted] the NMI also opined that [redacted] The Parties held follow-up meetings on 18 December 2008, and the Parties' factual accounts of what occurred differ.[45] In any event, no agreement was reached and the Registration Office ultimately recommended to the Minister to deny the Detralex market authorisation renewal. The Minister did so by Decision No. OR/0114/08 dated 19 December 2008. The Minister also denied Servier's application for reconsideration on 25 February 2009.[46]

[redacted]

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44 Statement of Claim, paras. 143-147.

45 According to Servier, for example, the Registration Office's tentative decision of 28 November 2008 was delivered to it "shortly before" the 18 December 2008 meeting, while the clerks of the Office stated during the meeting that the Office had formed a view that it would not be able to discuss further. Statement of Claim, paras. 130-132. By contrast, Poland asserts that Servier received the Registration Office's 28 November decision sufficiently in advance to be able to respond, which it did "more than two weeks before this meeting took place." Statement of Defence, para. 153.

46 Statement of Defence, paras. 156-157.

[redacted]

C. THE EURESPAL SYRUP HARMONISATION PROCESS

82. The active substance fenspiride hydrochloride (or simply "fenspiride") was introduced onto the Polish market on 30 January 1998 when Eurespal, in both syrup and tablet form, was first registered. Fenspiride is a treatment for respiratory tract disorders. Both forms of Eurespal were registered pursuant to the old 1991 Pharmaceutical Act. Both forms were prescription only and their respective registration certificates were valid until 31 March 2000. On 17 February 2000, the registration certificates were duly extended to 30 January 2003. On 12 February 2003, pursuant to Article 14(4) of the Act on Introductory Provisions and Article 29(3) of the Pharmaceutical Law, the marketing authorisations for both Eurespal Syrup and Eurespal Tablets were renewed until 30 January 2008.

83. On 29 November 2006, Servier submitted the Eurespal Syrup Harmonisation Application, which was received by the Registration Office on 1 December 2006. In that application, Servier sought to renew the marketing authorisation for use in both the adult and paediatric populations. The term "paediatric population" refers to patients between the ages of one day and 18 years of age, and is usually divided in subgroups that account for the different characteristics (weight, metabolism, etc.) of the various stages of human development.[48]

84. On 28 June 2007, the Registration Office's Clinical Documentation Assessment Section ("CDAS") issued its initial assessment, in which it concluded tha[redacted]

85. On 9 August 2007, Servier filed its first supplement of clinical materials, including a statement by a clinical expert,[redacted] The CDAS responded on 25 October 2007, indicating that[redacted]

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47 Statement of Defence, para. 159.

48 Statement of Defence, paras. 229-230.

49 Statement of Defence, para. 234.

[redacted]

86. Servier submitted a new clinical expert report by [redacted] on 18 December 2007. Once again the CDAS issued a report on 24 January 2008, where it observed that [redacted]

87. Servier filed an updated clinical expert report, prepared again by [redacted] and dated 16 August 2008. By that time, a "Harmonisation Team" had been established by the Respondent to ensure that all potentially negative decisions by the Registration Office were re-reviewed and that there was a valid basis for any refusal of a harmonisation application. That Team found that [redacted]

88. On 15 October 2008, Servier submitted one final set of supplemental materials, including a clinical expert report by [redacted] Again this report was found to be

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[50] Statement of Defence, para. 238. The Respondent notes that [redacted]

[51] Statement of Defence, para. 239.

[52] Statement of Defence, para. 241 (quoting Exhibit R-89, Assessment of the second supplement of clinical documentation prepared by the Registration Office dated 24 Jan. 2008).

[53] Statement of Defence, para. 246 (quoting Exhibit C-82, EU Pharmaceutical Directive, Annex I, Section 5.2.5.1).

[redacted]

89. Thus, while the evidence submitted by Servier ultimately was considered [redacted] Thus, upon the recommendation of the Registration Office, the Minister of Health issued Decision No. OR/0031/08 on 20 November 2008, denying the Application for Harmonisation of Eurespal Syrup.[55] [redacted]

[redacted]

90. Servier's motion for reconsideration of the Decision, which was filed on 18 December 2008, was denied by the Minister on 21 May 2009 on grounds of [redacted]

[redacted]

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54 Statement of Defence, para. 248.

55 Statement of Defence, paras. 249-250.

56 Statement of Defence, para. 254.

57 Reply, paras. 97-98.

58 [redacted]

92. [redacted][59]

93. [redacted][61]

94. [redacted]

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[59] Reply, para. 190.

[60] Statement of Defence, para. 189. [redacted]

[61] Statement of Defence, para. 190.

[62] Statement of Defence, para. 191.

[63] Statement of Defence, para. 192 [redacted]

[redacted][64]

95. [redacted][67]

96. [redacted]

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64 Statement of Defence, para. 193.

65 Statement of Defence, para. 194.

66 Reply, para. 102.

67 Reply, para. 108.

68 Statement of Defence, para. 195.

69 Reply, paras. 103-104.

70 Statement of Defence, para. 195.

[redacted][72]

97. [redacted][73]

98. [redacted]

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71 Statement of Defence, para. 196.

72 Reply, paras. 111-112.

73 Statement of Defence, para. 197.

74 Statement of Defence, para. 199.

75 Statement of Defence, para. 200.

76 Reply, para. 113.

77 Reply, para. 114.

78 Statement of Defence, para. 200.

[redacted]

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79 Statement of Defence, para. 201.

80 Statement of Defence, para. 200.

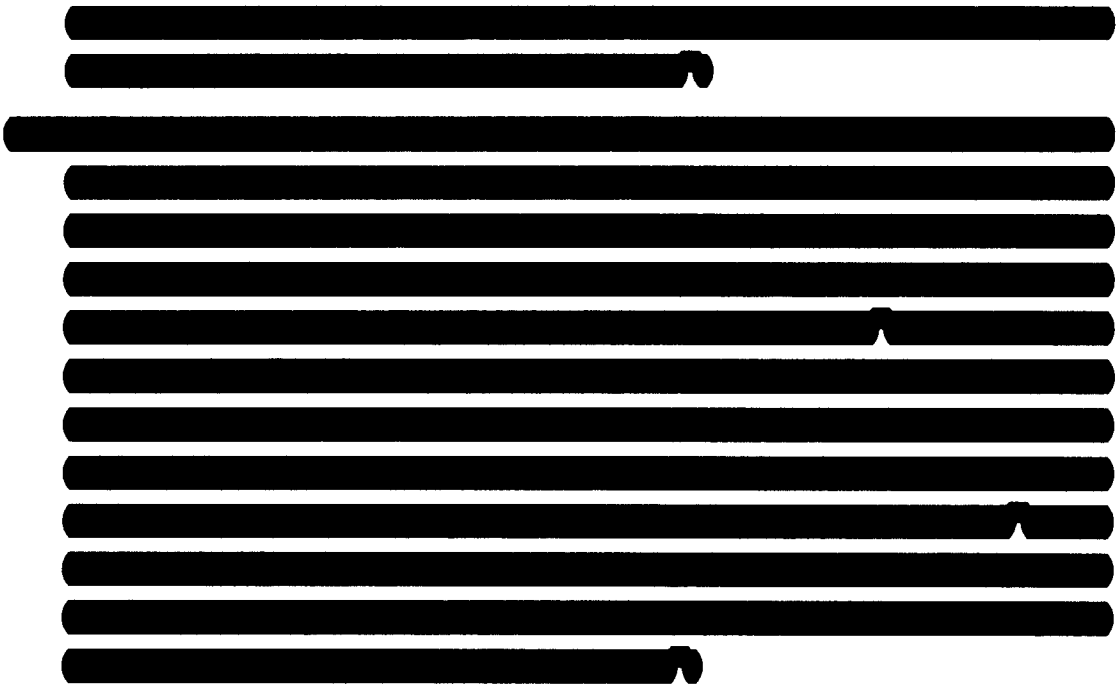
81 Statement of Defence, paras. 203-204.

82 Reply, para. 109.

83 Reply, para. 109 (quoting Exhibit C-126).

84 Reply, para. 115.

85 Statement of Defence, paras. 274-275.



E. PELETHROCIN

102. The Parties dispute the facts surrounding the Polish Government's licensing in 2002 of a pharmaceutical product called Pelethrocin, by the Greek company HELP S.A. Pharmaceuticals ("HELP"), as a generic to Detralex, and Pelethrocin's subsequent harmonisation.[90] The Parties agree that Pelethrocin is represented and marketed in Poland by the Polish company Blubit sp. z.o.o. ("Blubit").[91] In addition, Servier contends that Blubit is the "real party in interest" with respect to Pelethrocin, and that Blubit, rather than HELP S.A., instigated proceedings against Servier concerning Detralex and Pelethrocin.[92] Poland for its part denies Servier's allegations that the agency agreement by which HELP authorised Blubit to represent it in Poland in connection with its registration of Pelethrocin, or the power of attorney granted by HELP to Blubit render Blubit the "real party in interest."[93]

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86 Statement of Defence, paras. 276-281.

87 Statement of Defence, para. 205.

88 Statement of Defence, para. 206.

89 Statement of Defence, para. 207.

90 Statement of Claim, para. 67.

91 Statement of Claim, para. 67; Rejoinder, para. 91.

92 Reply, paras. 89-90.

93 Rejoinder, para. 91.

103. The Parties hold divergent views as to the Polish legal framework governing generics at the time of Pelethrocin's registration. Servier cites to Article 15 of the Pharmaceutical Law. Under the Pharmaceutical Law, a generic product may be registered without the clinical trial and other scientific data demonstrating safety and efficacy that is required from the original producer. The generic producer may also sell the generic as "equivalent to" the original product.[94] However, it must be shown for the generic that the active ingredient is exactly the same as that of the original, and that the generic is bioequivalent to the original (*i.e.*, that ingestion of the generic produces comparable levels of the active ingredient in patients' bloodstreams).[95]

104. By contrast, Poland contends that the "more stringent and EU-compliant" Pharmaceutical Law was not the basis for Pelethrocin's registration.[96] That is, although the Pharmaceutical Law was enacted on 6 September 2001, it did not enter into force until 1 October 2002. Actually, the Law provided that, until 30 June 2003, applications for registration would continue to be made under the 1991 Pharmaceutical Act.[97] Indeed, the registration certificate for Pelethrocin indicates that it was registered on 24 April 2002 under the 1991 Pharmaceutical Act.[98] Under this Act, the Registration Committee "had a broad discretion to 'consider as sufficient, in part or in full, the results of laboratory tests and clinical trials as provided by the manufacturer.'"[99]

105. The Parties also disagree over the composition of Pelethrocin. Servier states that it learned of the registration of Pelethrocin in May 2003, when it received a letter from the Polish Chief Pharmaceutical Inspectorate, indicating that the marketing authorisation holder for Pelethrocin had tested Detralex and found that [redacted]

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94 Statement of Claim, para. 70.

95 Statement of Claim, paras. 69, 71.

96 Statement of Defence, paras. 294-295.

97 Statement of Defence, paras. 296, 299.

98 Statement of Defence, para. 295.

99 Statement of Defence, para. 296 (quoting 1991 Pharmaceutical Act).

100 Statement of Claim, paras. 72-73.

[redacted]

107. Servier argues that Poland's decision to register Pelethrocin as a generic to Detralex, without requiring a full dossier of pre-clinical studies and clinical trials, was contrary to the Pharmaceutical Law.[105] [redacted]

108. The harmonisation application for Pelethrocin as a generic of Detralex was filed on 27 December 2007 and granted a year later.[110] Servier states that, although the Diosmin Advisory Group found that Pelethrocin did not meet the qualitative requirements of the

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101 Statement of Claim, para. 76.

102 Statement of Defence, para. 297.

103 Statement of Defence, para. 298 (quoting Exhibits C-5 and C-10).

104 Rejoinder, paras. 93-95.

105 Statement of Claim, paras. 75, 77.

106 Statement of Claim, para. 78; Rejoinder, para. 127.

107 Rejoinder, para. 127 (quoting Exhibit C-20).

108 Rejoinder, para. 127.

109 Statement of Claim, para. 78.

110 Reply, para. 92; Rejoinder, paras. 96-97.

Phar. Eur., it granted the application and ordered Blubit to change the documentation to state the active ingredient as Diosminum 500 mg and to change the application category to well-established use.[111] Moreover, in November 2008, Poland granted Blubit's application for permission to supplement its harmonisation application after marketing authorisation had been granted. Harmonisation renewal was granted on 10 December 2008 "despite a lack of information on the manufacturing method, the test methods and reference standards, the composition of the actual product and a range of other issues."[112]

F. DIOSMINEX

109. The Parties agree that Annex XII of the Accession Treaty contains a "grandfathering" provision that permits medicinal products validly marketed in Poland before accession to continue to be marketed in Poland after accession, until harmonisation. The products were simply required to be listed in Annex XII, and to be harmonised, or reviewed for compliance with EU standards, by 31 December 2008.[113]

110. However, Servier states that the Polish authorities included in Appendix A to Annex XII a "large number of local products that lacked any marketing authorisation at time of signing the Accession Treaty [on 16 April 2003], and in many instances did not even physically exist at the time when the list was prepared. . . . [T]he only 'evidence' of their existence was . . . an application to register a non-existent product under the previous rules in Poland."[114] The Polish Ministry of Health then issued marketing authorisations for many of these products in the last days before accession, with recommendations to provide documentation and study results at a later point.[115] Servier alleges that these marketing authorisations with recommendations were granted "despite unequivocal advice from lawyers in the Ministry and the Office of Registration that doing so was contrary to Polish law."[116] In response, Poland accuses Servier of providing an incomplete and misleading translation of the Audit Protocol it cites in support of its argument, because Servier omitted certain paragraphs which find that the issuance of those authorisations actually was valid under Polish law.[117]

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[111] Reply, para. 93.

[112] Reply, paras. 94-96.

[113] Statement of Claim, paras. 80-81, 87; Statement of Defence, paras. 292, 304.

[114] Statement of Claim, paras. 88-89; Claimants' First Post-Hearing Submission, paras. 26-27.

[115] Statement of Claim, paras. 90-94; Claimants' First Post-Hearing Submission, paras. 26-27.

[116] Reply, para. 74 (quoting Exhibit C-138, Protocol of Control carried out by the Supreme Chamber of Control at the Office for Registration of Medicinal Products, Medical Devices and Biocides in Warsaw).

[117] Rejoinder, paras. 72-74.

Servier posits, however, that in 2006 the Polish Supreme Chamber of Control also criticised these authorisations, and the Polish Administrative Courts have found them to be "legally not compliant", although "diverging opinions" have also been expressed.[118]

111. As discussed in more detail further below, on 22 December 2010, the Court of Justice of the European Union ("CJEU") issued a judgment finding that Poland's issuance of marketing authorisations with recommendations, although consistent with Polish law, violated EU law where the recommendations were only satisfied after Poland's accession.[119] The Parties disagree over numerous aspects of the CJEU proceedings, including the import of certain arguments by Poland,[120] and the implications of the CJEU's judgment on the marketing authorisation for the drug Diosminex.[121]

112. The Polish drug Diosminex, currently the main market competitor of Detralex, is among the products registered under the "authorisation with recommendations" procedure described above. The application for Diosminex was submitted on 30 September 2002 under the 1991 Pharmaceutical Act.[122] Servier states that the information submitted in support of its authorisation was "minimal", while the recommendations issued in respect of it were that "the applicant produce in the future a copy of the drug master file, a verified statement of the active ingredient, a detailed description of the method of production of the medicinal product, expert reports showing bioequivalence of Diosminex with the original drug and tests of the composition of Diosminex."[123] The Diosminex marketing authorisation was issued the day before accession, 30 April 2004, with the condition that the drug could be marketed only after compliance was demonstrated with the recommendations issued.[124] Eleven days earlier, on 19 April 2004, the Registration Office requested the submission of critical documents and data in connection with the authorisation of Diosminex within seven days, and stated that all remaining documentation requirements would be described in the

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118 Statement of Claim, paras. 95, 96, n. 124; Statement of Defence, paras. 303-304.

119 Reply, paras. 70-73; Rejoinder, paras. 67-68; Claimants' First Post-Hearing Submission, para. 26.

120 *See* Reply, para. 71; Rejoinder, paras. 69-71.

121 Reply, para. 70; Rejoinder, para. 67.

122 Statement of Defence, paras. 299-300.

123 Statement of Claim, para. 97.

124 Statement of Defence, paras. 300, 302, 304.

authorisation.[125] Servier complained to the Ministry of Health several times regarding the registration of Diosminex, stating in one letter that it constituted a "gross breach of law."[126]

113. The Parties disagree as to the chemical composition of Diosminex. According to Servier, after the registration of Diosminex, it could not be shown that the product was bioequivalent to Detralex, and Poland subsequently waived the requirement.[127] Servier asserts, further, that the documents produced in this arbitration have not shown that Diosminex contains the same active ingredient as Detralex.[128] According to Poland, however, in the same February 2007 letter to the Ministry of Health in which Servier complained that the registration of Diosminex constituted a "gross breach of law,"[redacted]

114. The Parties agree that Diosminex was not available on the Polish market until 2 February 2007, after the Polish authorities confirmed that it had fulfilled its recommendations.[132] Servier states that the Polish Ministry of Health declined to consider the merits of Servier's challenge to the Diosminex authorisation, because Servier allegedly did not have a legal interest in raising such a challenge—a decision which was criticised by the Regional Administrative Court in Warsaw in its judgment of 12 March 2009.[133] Despite the Administrative Court's determination, on reconsideration of Servier's motion, the Ministry of Health again rejected Servier's challenge.[134]

115. The harmonisation application in respect of Diosminex was filed on 4 December 2007, on the basis of "well established use" rather than as a generic to Detralex.[135] Its active

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[125] Reply, para. 76.

[126] Rejoinder, para. 128 (quoting Exhibit C-22).

[127] Reply, para. 78.

[128] Reply, para. 79.

[129] Rejoinder, para. 128 (quoting Exhibit C-22).

[130] Rejoinder, para. 128 (quoting Exhibit C-22).

[131] Rejoinder, para. 129.

[132] Statement of Claim, para. 100; Reply, para. 80.

[133] Statement of Claim, paras. 101-103.

[134] Statement of Claim, para. 104.

[135] Statement of Claim, para. 104; Reply, para. 81.

substance was stated to be diosmin; however, Servier points out the clinical studies provided with the Diosminex application actually concerned Detralex and MPFF, not diosmin.[136] According to Servier, the Diosmin Advisory Team engaged in limited discussion of the merits of the Diosminex application. The minutes of the 7 February 2008 Diosmin Advisory Team meeting refer to a "decision . . . issued already some time ago to classify the drug to the well-established use category"—of which decision, however, there is no record in the files of the Diosmin Advisory Team or in the Diosminex harmonisation file. [137] Servier states that the only discussion of the substance of the Diosminex application "appears in a conclusory resolution during the meeting on August 11, 2008 that the name of the active substance of Diosminex should be Diosminum 500mg, in line with European Pharmacopoeia terminology and that the application should be classified in the well-established use category."[138] A final assessment of documentation, undertaken by the Registration Office on 6 November 2008, shows that further "supplementations by way of post-registration amendments" were required after Dosminex's authorisation.[139] Diosminex's harmonisation renewal was granted on 16 December 2008.[140]

116. Poland denies each of these factual allegations. Regarding the minutes of the 7 February 2008 Diosmin Advisory Team meeting, Poland argues that these show that the Team "engaged in a thorough, full and detailed discussion of the various registration issues presented by all diosmin products"; that the Team "discussed all diosmin based drugs at the same time"; and that the "national origin of various applicants was never discussed during their extensive meetings."[141] Moreover, Poland notes that statements in Servier's Reply confirm that the original decision to classify the drug in the well-established use category was made by the Diosminex applicant, LEK-AM, and not by the Polish authorities, which merely reviewed the application.[142] Poland asserts that the substance of the Diosminex application was discussed not only during the 11 August 2008 meeting, but again "in detail" during the Diosmin Advisory Team meeting of 30 September 2008.[143] Addressing Servier's contention that Diosminex's renewal was granted by relying on Servier's scientific studies

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136 Reply, para. 81.

137 Reply, paras. 82-83.

138 Reply, para. 84.

139 Reply, para. 85.

140 Reply, para. 86.

141 Rejoinder, para. 79.

142 Rejoinder, paras. 80-82.

143 Rejoinder, para. 83.

on MPFF, Poland states that [redacted]

G. PROCORALAN

118. The Parties offer differing accounts of events regarding Procoralan, a drug manufactured by Servier and used to treat angina pectoris, which had received authorisation to be marketed in all 27 EU countries, including Poland, by October 2005.[147] In October 2007, Procoralan was removed from a list of reimbursable drugs published by the Ministry of Health in a draft regulation, but was restored to this list on 2 November 2007, after alleged interventions by Servier.[148]

119. According to Servier, later in 2007, the removal and restoration of Procoralan became the subject of a "hotly contested debate" between the newly elected political party and the incumbent administration, which had taken the decisions.[149] Servier states that, "[f]ollowing the election, Polish authorities engaged in a persistent campaign to denigrate the drug and demonstrate (against all evidence to the contrary) that the Procoralan reimbursement decision . . . was unjustified."[150] On 14 May 2008, Servier was notified that Procoralan would be the subject of evaluation proceedings before the Polish Health Technology Assessment Agency ("HTAA"). Servier states that, the next day, the director of the agency issued an opinion concluding that Procoralan should not be reimbursed, stating that "a more

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144 Rejoinder, paras. 84-88.

145 Rejoinder, para. 130.

146 Rejoinder, paras. 131-134.

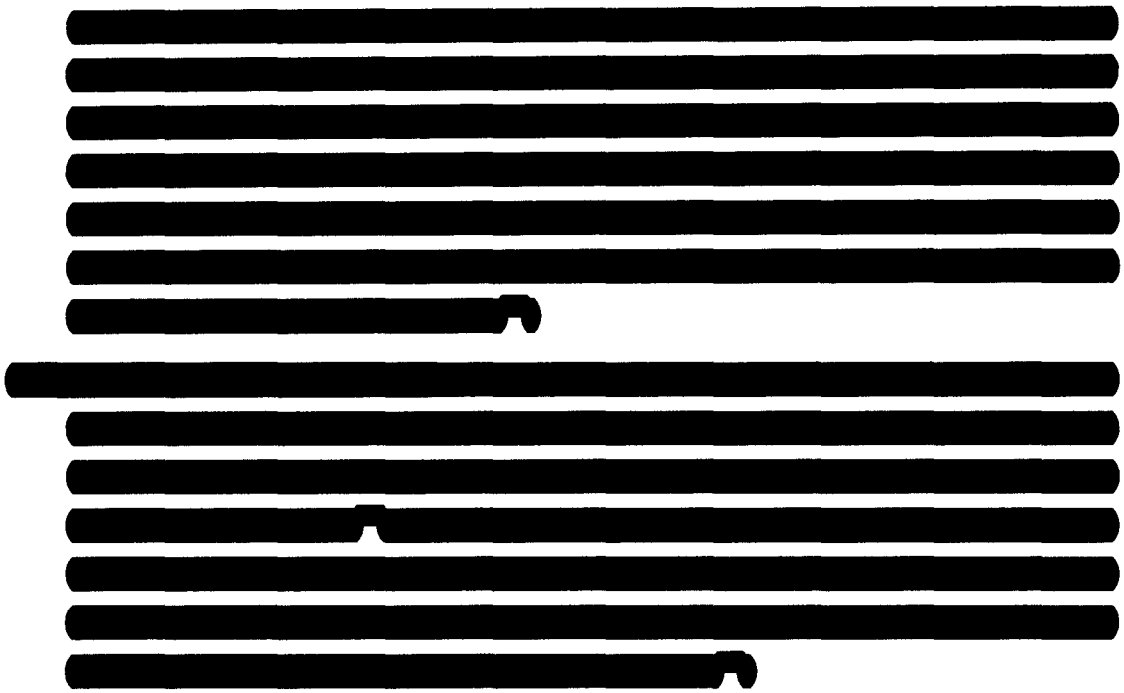
147 Statement of Claim, para. 105; Statement of Defence, para. 309.

148 Statement of Claim, para. 106; Statement of Defence, paras. 311, 313.

149 Statement of Claim, para. 107.

150 Statement of Claim, para. 107.

detailed analysis . . . [does not] seem[] to be necessary given the evidence on hand so far."[151]



121. The Parties also present different accounts of an independent investigation conducted by the Polish Supreme Audit Chamber ("NIK"), the results of which are dated 1 July 2008. According to Servier, the investigation was of the "Procoralan reimbursement matter." No misconduct was found in relation to Procoralan, and the public controversy was attributed to the lack of transparency surrounding reimbursement decisions.[155] By contrast, Poland states that the NIK actually investigated the "observance of certain statutory procedures relating generally to the preparation of the Regulation of 2 November 2007 (affecting several drugs in addition to Procoralan), and that the NIK found 'a number of irregularities'" in those procedures.[156] Servier counters that, in a decision dated 12 November 2010, the Appellate Prosecutor's Office in Krakow discontinued its inquiry into charges of corruption relating to the inclusion of Procoralan on the Reimbursement List.[157]

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[151] Statement of Claim, para. 110 (quoting Exhibit C-37, Opinion of the Polish HTAA dated 15 May 2008); *see also* Statement of Defence, para. 314.

[152] Statement of Claim, paras. 111-115; Reply, paras. 64-65.

[153] Statement of Defence, paras. 319-320.

[154] Statement of Defence, paras. 316-317.

[155] Statement of Claim, para. 108; Statement of Defence, para. 314.

[156] Statement of Defence, para. 318 (quoting Exhibit C-38, Supreme Audit Chamber's letter to the Minister of Health presenting results of an audit dated 1 July 2008).

[157] Reply, para. 62.

122. The Parties also offer contrasting versions of the timeline of events surrounding the Detralex and Eurespal non-renewal decisions, in relation to the Procoralan events. Servier states that the Diosmin Advisory Team first discussed Detralex in July 2007, and found that the documentation "unequivocally indicates the safety of . . . Detralex."[158] During the next discussion in February 2008, "after the political storm concerning Procoralan broke," the "tone was quite different, with denial of harmonisation to Detralex and potential litigation resulting from the group's decisions suddenly on the agenda."[159] Servier submits that in June 2008, one month after the HTAA report, Poland suggested to local manufacturers of generics of Eurespal Syrup that they should change the reference product to Pneumorel Syrup, which is the French commercial name for the same drug.[160]

123. By contrast, Poland states that the Registration Office first identified deficiencies with the Detralex Harmonisation Application in a memorandum dated 28 December 2005, in which the Office noted that [redacted] Citing a lack of connection between the events surrounding Procoralan and the issues in this arbitration, on 19 July 2010 Poland requested Servier to confirm in writing that it was "no longer advancing any claims in relation to their alleged investment in Procoralan and, therefore, the allegations set out in the Notice of Arbitration and Statement of Claim relating to Procoralan are irrelevant to the issues in the case and do not in fact need to be considered by the Tribunal."[162]

H. REGISTRATION OF PULNEO, ELOFEN, AND FENSPOGAL SYRUPS

124. The Parties disagree as to certain facts surrounding the issuance, shortly after the Eurespal non-renewal decision, of marketing authorisations for three drugs produced by Polish manufacturers with the same active substance as Eurespal and offered in the same form and

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[158] Reply, para. 66 (quoting Exhibit R-77, Coordinator's Report on the Activites of the Diosmin Advisory Team in July 2007, pp. 1-2).

[159] Reply, para. 66.

[160] Reply, para. 66.

[161] Rejoinder, para. 59.

[162] Exhibit R-220, Allen & Overy LLP letter to SCP Salans dated 19 July 2010; Rejoinder, para. 56.

dosage. On 3 March 2009, a marketing authorisation was issued to Aflofarm Farmacja Polska Sp. z.o.o. for the product Pulneo, and to Polfarmex S.A. for the product Elofen, both of which, like Eurespal, contain the active substance Fenspiride hydrocholoride, and are offered in syrup form at the dosage of 2 mg/ml. In the marketing authorisation application for each, Eurespal is listed as the reference product, but this was changed on 6 June 2008 and 5 July 2008, respectively, to Pneumorel, which is the name used by Servier in France for Eurespal Syrup.[163]

125. Servier states that the Ministry of Health never answered Servier's letter of 9 April 2009 requesting an explanation as to why Pulneo was registered but Eurespal Syrup was not.[164] Similarly, Servier's 30 April 2009 request to the Ministry for an explanation as to the registration of Elofen was not answered.[165] On 23 September 2009, a marketing authorisation was issued to the Polish company Farmaceutyczna Spóldzielnia Pracy "Galena" for Fenspogal. The application named Eurespal as the reference product; this was changed, in mid-2008, to Pneumorel.[166]

126. Poland states that the reference product for each of the Polish products was changed by the applicants, because the Pharmaceutical Law required products to be successfully harmonised before they could be used as reference products.[167] In addition, under EU law, the benefits and risks of a generic product must be assumed to be the same as the reference product.[168] By contrast, under the Polish procedure, Servier's application for the renewal of a marketing authorisation for an original drug did not permit the Registration Office to assume that the benefits and risks of Eurespal were the same as those of another product. Instead, these were required to be established by the presentation of reliable clinical data.[169]

127. [redacted] At the same time,

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[163] Statement of Claim, paras. 162-164, 166-168; Statement of Defence, paras. 264-265, 268.

[164] Statement of Claim, para. 165.

[165] Statement of Claim, para. 168.

[166] Statement of Claim, paras. 169-170; Statement of Defence, paras. 264-265, 268.

[167] Statement of Defence, paras. 266-277. Poland states that the Registration Office informed two of the applicants of the possibility of changing their applications because of the expiration of the 210 days for decision on their applications, which was due to delays in the harmonisation of Eurespal. Statement of Defence, para. 266.

[168] Statement of Defence, paras. 267-268.

[169] Statement of Defence, para. 269.

[170] Statement of Claim, para. 171.

according to an official IMS Health report, in April 2010 Pulneo was ranked among 20 pharmaceutical products having the fastest and largest growth rate in Poland.[171]

I. CJEU DECISION ON DRUG MARKETING AUTHORISATIONS IN POLAND

128. As noted above, Servier argues that by its judgment dated 22 December 2010, the CJEU found that Poland had violated EU law by including in its Appendix A to Annex XII of the Accession Treaty certain products like Diosminex, for which insufficient documentation had been submitted, or which may not have existed at all. In Servier's view, the CJEU noted that these products had been hastily granted "marketing authorisations" under a procedure that was not reflected in Polish law, and that the "authorisations" were conditioned upon the applicant later presenting sufficient documentation to justify placing the product on the market.[172]

129. The Respondent counter-argues that Servier misrepresents both the content and import of the CJEU judgment. The judgment makes no reference to what Servier calls "ghost products" nor is there a single reference to Diosminex. The CJEU takes issue with two decisions by the Polish authorities in 2004, some four years before Poland decided not to renew marketing authorisations for Detralex and Eurespal syrup. The Court also addresses the registration of certain generics of a drug called Plavix. Moreover, the CJEU found that Poland's issuance of marketing authorisations with recommendations, while consistent with Polish law, was inconsistent with EU law to the extent those recommendations were only satisfied after Poland's accession on 1 May 2004. Thus, according to the Respondent, the CJEU judgment is plainly inapposite to the issues at bar. [173]

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[171] Statement of Claim, para. 173.

[172] Reply, paras. 71-72.

[173] Rejoinder, paras. 67-74.

V. THE PARTIES' ARGUMENTS

130. The summaries of the Parties' arguments set out below are without prejudice to the Parties' full arguments as submitted in written pleadings and presented at the hearing, which the Tribunal has taken into full consideration in making its determinations.

A. JURISDICTION

1. Whether the Claimants have established that they made investments that are protected under the Treaty

(1) The relevant legal standard

Servier's Arguments

131. Servier contends that its burden is to show that it held investments protected under the Treaty, as defined by the Treaty.[174] Servier rejects Poland's argument that Servier must prove that its investments are investments "protected as a matter of Polish law and . . . demonstrate the scope of such rights under Polish law."[175] Servier submits that the final two paragraphs of Article 1 of the Treaty make it clear that it is not the existence of an asset, but the legality of its admission or acquisition that is to be judged under national law.[176]

132. Servier also contests Poland's argument that the national laws of a host State must be applied to establish a territorial nexus between the investment and the host State.[177] Servier submits that the "territorial nexus" simply means that the Treaty applies to foreign, as opposed to domestic investment, and requires an investor to commit resources in the territory of the host State, as opposed to being wholly confined to the territory of another State.[178]

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[174] Reply, paras. 128, 132, 142.

[175] Reply, paras. 127-128 (quoting Statement of Defence, para. 338).

[176] Reply, para. 143.

[177] Reply, para. 145.

[178] Reply, para. 145.

Poland's Arguments

133. Poland asserts that in order for this Tribunal to find jurisdiction, Servier must prove that (1) Servier companies have protected property rights as a matter of Polish law; and (2) those property rights are protected investments under the Treaty.[179]

134. Poland argues that the question whether the Claimants have acquired proprietary rights in any of the alleged investments is a matter of Polish law, not international law.[180] Poland cites Article 1 of the Treaty which provides: "The term 'investment' shall mean assets such as property, rights and interests of any kind related to an economic activity in any sector, in accordance with the legislation of the Contracting Party in whose territory...the investment has been made... ."[181] Poland asserts that the Treaty does not provide any guidance as to how a proprietary interest in the protected investments is acquired by an investor, nor to the scope of such rights.[182] Thus, Polish law supplements and provides substance to the broad language of Article 1 of the Treaty.[183]

135. According to Poland, once domestic law has been used to determine the precise nature of the proprietary rights, the Tribunal may consider whether those rights fall within the Treaty definition of "investment".[184] Poland also points out that there is "abundant authority" in support of its position on this issue, and "no authority" in support of Servier's.[185] It also warns of practical difficulties with Servier's approach, which "does not provide for any criteria against which an assertion that a particular subject is protected under Article 1(1) of the Treaty can be tested."[186] In Poland's view, "[o]nly national law is capable of filling the lacuna."[187]

136. Poland submits that the national laws of a host State must be applied because the Treaty requires a territorial nexus between the investment and the host State.[188] [redacted]

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179 Statement of Defence, para. 326.

180 Statement of Defence, paras. 326-338; Rejoinder, para. 139; Respondent's First Post-Hearing Brief, paras. 14-15.

181 Statement of Defence, para. 329.

182 Rejoinder, para. 139.

183 Rejoinder, para. 141.

184 Rejoinder, paras. 141-145.

185 Respondent's First Post-Hearing Brief, para. 15.

186 Respondent's First Post-Hearing Brief, para. 15.

187 Respondent's First Post-Hearing Brief, para. 15.

188 Statement of Defence, para. 337.

[redacted]

(2) Servier's identification of its Claimed Investments

Servier's Arguments

[redacted]

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189 Statement of Defence, paras. 338, 346-348.

190 Citing Exhibits C-3, C-4, and C-9.

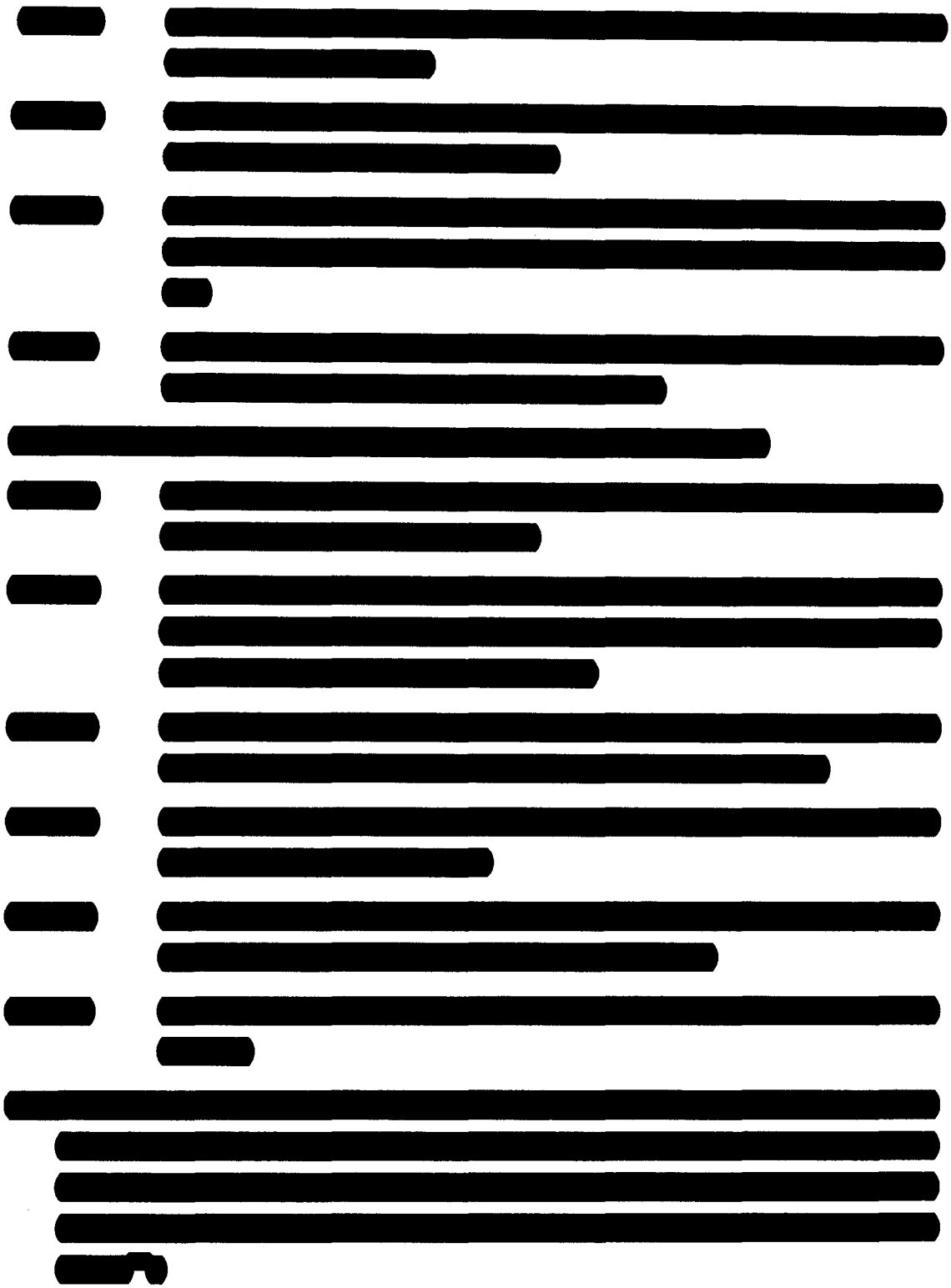
191 Citing Exhibits C-113 and C-109, paras. 5-19.

192 Citing Exhibit C-114.

193 Citing Exhibits C-40, C-41, C-48, and C-114.

194 Citing Exhibit C-115.

195 Citing Exhibits C-116 and C-108, paras. 15-17, 20-21, 23.



[196] Article 1.1(a) of the France/Poland BIT defines "investments" as "[m]ovable and immovable property and all other real rights such as mortgages, preferences, usufructs, sureties and similar rights....". Article 1.1(b) defines "investments" as "[s]hares, issue premiums and other forms of participation, even minority or indirect, in companies constituted in the territory of either Party." Exhibit R-1.

Poland's Arguments

141. Poland asserts that Servier has failed to set out with any precision or consistency what its investments in Poland are.[197]

142. The Parties' positions concerning each of Servier's Claimed Investments will now be summarised in turn.

(3) Whether the Claimed Investments belong to the Claimants and are protected by Polish law

[redacted]

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197 Statement of Defence, paras. 339-345, 354-355.

198 Reply, para. 151.

199 Reply, para. 152.

200 Statement of Defence, paras. 349-352. Poland submits tha[redacted]

201 Statement of Defence, para. 351.

[redacted]

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202 [redacted]

203 Statement of Defence, para. 352.

204 [redacted]

205 Reply, para. 174.

206 *See* Exhibit C-172.

[redacted]

207 Reply, para. 175.

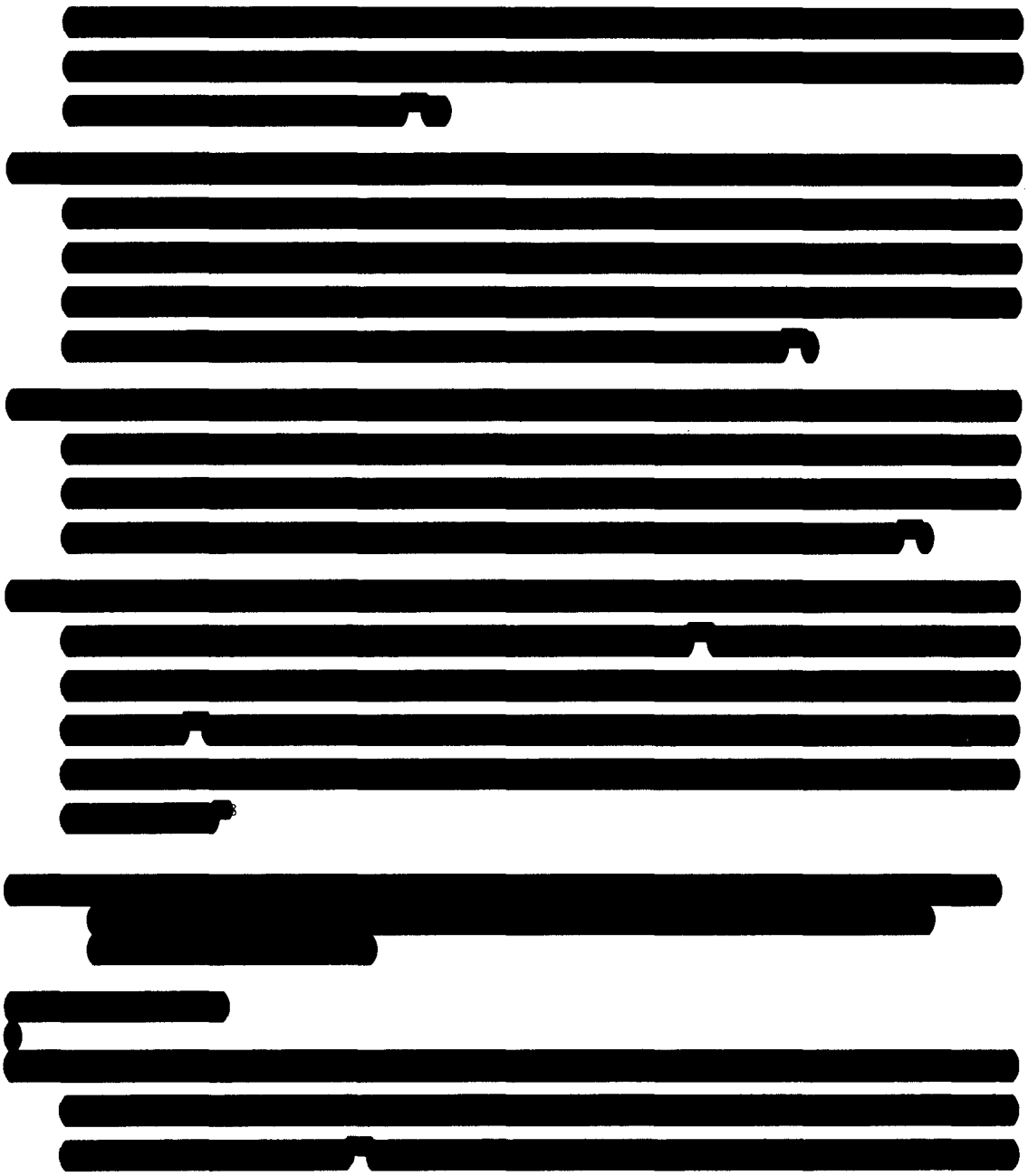
208 Reply, para. 176.

209 [redacted]

210 Claimants' Second Post-Hearing Submission, paras. 68-73.

211 Statement of Claim, para. 188.

212 Statement of Defence, paras. 353, 356-357.



[213] Rejoinder, paras. 147-148 (quoting Exhibit C-173, Polish Supreme Court, Sudgementre Fabryka Puclelek: Litografii dated 4 Feb. 2005).

[214] Respondent's First Post-Hearing Brief, para. 16.

[215] Rejoinder, para. 151.

[216] Rejoinder, para. 150.

[217] Statement of Defence, para. 359; *cf.* Statement of Claim, para. 188.

[218] Statement of Defence, para. 360; *see also* Rejoinder, para. 150.

[219] Reply, para. 162; *see also* Expert Opinion o[redacted] para. 3.1.

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220 Reply, para. 160.

221 Reply, paras. 162-164.

222 Reply, paras. 160, 162-165.

223 Reply, paras. 166-167 (quoting Statement of Defence, para. 368).

224 Reply, para. 166.

225 Reply, para. 167 (citing Exhibit C-164).

226 Reply, para. 167.

227 Reply, para. 168.

228 Reply, para. 169.

229 Reply, para. 170.

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230 Reply, para. 171.

231 Reply, para. 172.

232 Statement of Defence, para. 362.

233 Statement of Defence, para. 362; Rejoinder, para. 156.

234 Statement of Defence, paras. 363-367, 372.

235 Statement of Defence, para. 368.

236 Rejoinder, paras. 154-155; Respondent's First Post-Hearing Brief, para. 17.

166. [redacted]

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237 Statement of Defence, para. 369.

238 Statement of Defence, para. 370.

239 Reply, para. 153.

240 Reply, para. 153 (quoting Statement of Defense, para. 375).

241 Reply, para. 154. Article 11(4) of the Act on Counteracting Unfair Competition of April 16, 1993, provides: "business secret shall mean an undertaking's publicly undisclosed technical, technological and organizational information or any other information having commercial value, in respect of which the undertaking took the necessary precautions to maintain its confidentiality."

242 Reply, para. 154.

[243] Reply, para. 158.

[244] Reply, para. 159 (citing Statement of Defense, para. 375 and Exhibits C-159, C-160, C-70, and C-210). *See also* Appendix 2 to Statement of Claim.

[245] Statement of Defence, para. 374.

[246] Rejoinder, para. 158; *see also* Statement of Defence, para. 374.

[247] Rejoinder, para. 160; Statement of Defence, para. 375.

[248] Respondent's First Post-Hearing Brief, para. 17.

[249] Rejoinder, para. 161.

[250] Statement of Defence, para. 375; Rejoinder, para. 162.

[redacted]

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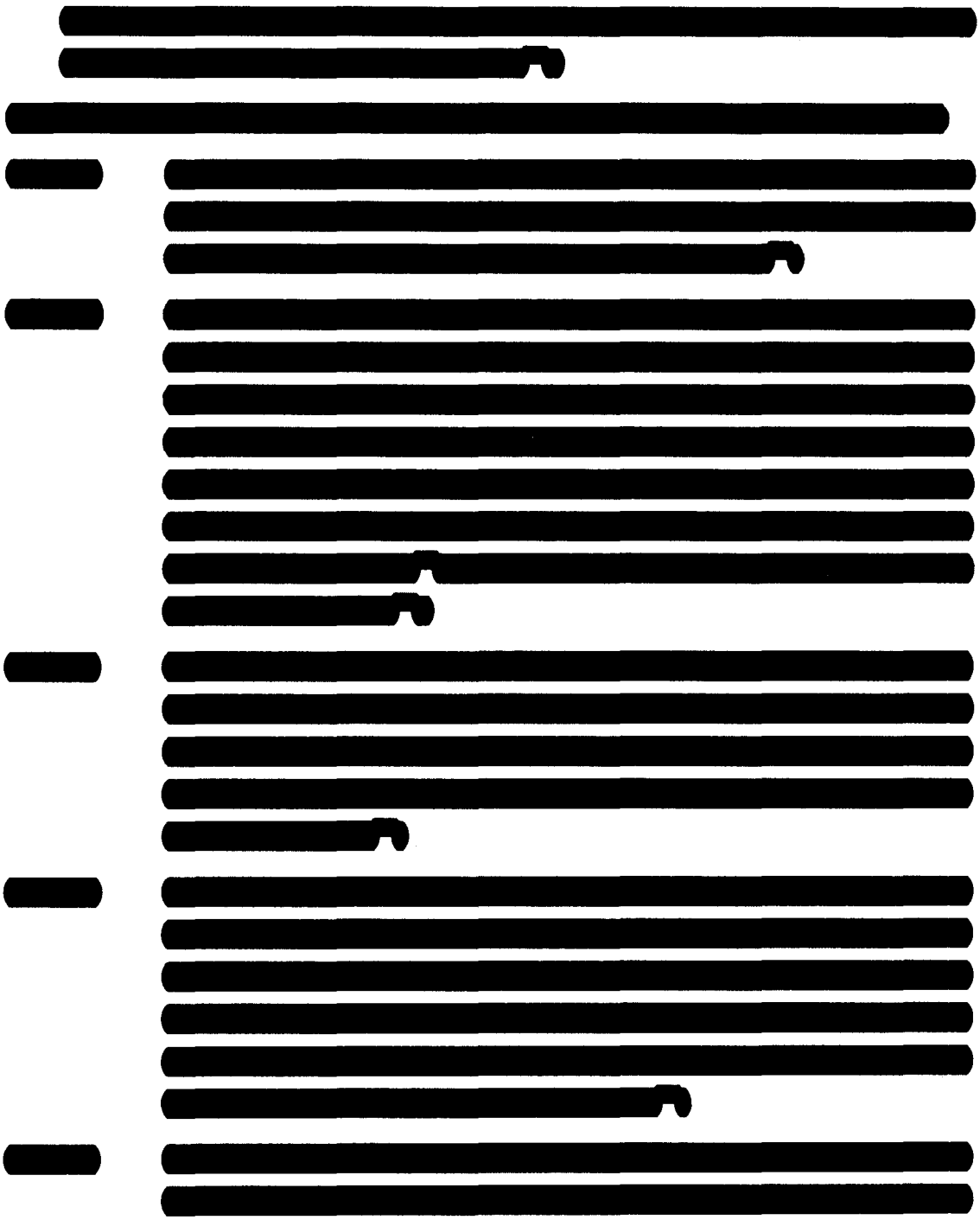
[251] Respondent's First Post-Hearing Brief, para. 17.

[252] Rejoinder, para. 163.

[253] Claimants' First Post-Hearing Submission, paras. 99-100; *see also* Claimants' Second-Post Hearing Brief, para. 66.

[254] Claimants' First Post-Hearing Submission, paras. 101-102.

[255] Claimants' First Post-Hearing Submission, para. 101.



[256] Claimants' First Post-Hearing Submission, para. 103.

[257] Claimants' Second Post-Hearing Submission, para. 75.

[258] Claimants' First Post-Hearing Submission, para. 104; Claimants' Second Post-Hearing Submission, para. 74.

[259] Claimants' Second Post-Hearing Submission, para. 67.

[260] Appendix 2 to Statement of Claim; Claimants' First Post-Hearing Submission, para. 105.

[261] Appendix 2 to Statement of Claim; Claimants' First Post-Hearing Submission, para. 106.

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262 Appendix 2 to Statement of Claim; Claimants' First Post-Hearing Submission, para. 107.

263 Respondent's Second Post-Hearing Brief, para. 2.

264 Rejoinder, paras. 164-166; Respondent's First Post-Hearing Brief, para. 6.

265 Rejoinder, para. 168. According to Poland, [redacted] *Id.*

266 Rejoinder, para. 169.

267 Rejoinder, para. 170.

268 Rejoinder, para. 170.

269 Rejoinder, para. 170.

270 Rejoinder, para. 176, referring to Statement of Claim, Appendix 2.

[271] Statement of Claim, Appendix 2; Respondent's Second Post-Hearing Brief, para. 3.

[272] Rejoinder, paras. 177-178; Respondent's Second Post-Hearing Brief, para. 3.

[273] Respondent's First Post-Hearing Brief, para. 7 (emphasis in the original).

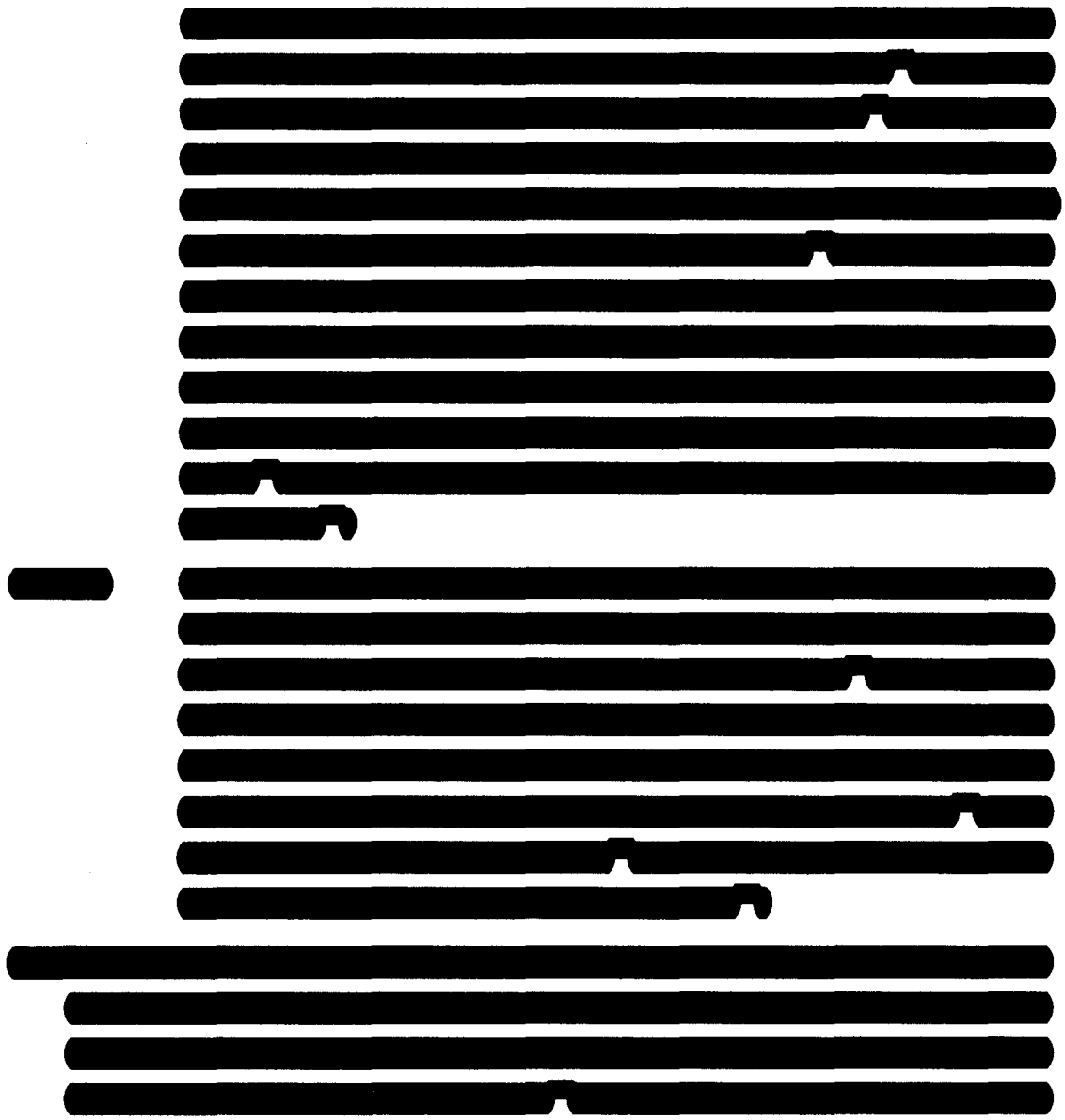
[274] Respondent's First Post-Hearing Brief, para. 8; Respondent's Second Post-Hearing Brief, para. 3.

[275] Respondent's Second Post-Hearing Brief, para. 3.

[276] Respondent's First Post-Hearing Brief, para. 9.

[277] Respondent's First Post-Hearing Brief, para. 9.

[278] Respondent's First Post-Hearing Brief, para. 10.



[279] Rejoinder, para. 179 (quoting Statement of Claim, Appendix 2).

[280] Rejoinder, para. 179 (citing Statement of Claim, Appendix 2).

[281] Rejoinder, paras. 180-182; Respondent's First Post-Hearing Brief, para. 11; *see also* Respondent's Second Post-Hearing Brief, para. 4.

[282] Rejoinder, para. 183; Respondent's First Post-Hearing Brief, para. 11; *see also* Respondent's Second Post-Hearing Brief, para. 4.

[283] Respondent's First Post-Hearing Brief, para. 11.

[284] Rejoinder, para. 184 (citing Statement of Claim, Appendix 2).

[285] Rejoinder, para. 186; *see also* Respondent's Second Post-Hearing Brief, para. 4.

[286] Rejoinder, para. 187.

[287] Rejoinder, para. 188.

[288] Rejoinder, para. 189.

[redacted]

(5) Whether there is a nexus between the Measures and the Claimed Investments

Servier's Arguments

185. Servier argues that the Treaty does not require the showing of a nexus between the Measures taken by Poland and the Claimed Investments.[290] Servier contends that, according to the wording of Article 8(1) and (2) of the Treaty, the required nexus relates to the relationship between the *dispute* and the investment, not the *measure* and the investment.[291] Servier claims that the required nexus is met in this case because the dispute arises out of Servier's investments in Poland and their dispossession through the measures at issue.[292]

186. Servier challenges Poland's assertion that its decisions not to renew the marketing authorisations represent nothing more than a "'mere causal connection', which did not give rise to a dispute relating to Servier's investment."[293] Servier alleges that Poland's Measures were addressed at and specifically targeted Servier with the purpose and effect of removing those drugs from the Polish market to the benefit of Polish companies.[294]

187. Servier also submits that Poland's "nexus" argument is not supported by the text of the Treaty.[295] Under Article 5, a State measure without compensation is a breach if it has "*the effect* of dispossessing investors of the other Party, either directly or *indirectly*, of investments belonging to them."[296] According to Servier, Article 5 provides that a measure violates the Treaty if it indirectly has the effect of dispossessing Servier of its investments.[297]

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289 Respondent's First Post-Hearing Brief, para. 12.

290 Reply, para. 197.

291 Reply, paras. 197-198.

292 Reply, para. 199.

293 Reply, para. 201.

294 Reply, para. 201.

295 Reply, para. 202.

296 Reply, para. 202 (emphasis in the original).

297 Reply, para. 202; Claimants' First Post-Hearing Submission, para. 120. In this regard, Servier also disputes Poland's reliance on the arguments made by the U.S. Government in *Methanex v. United States of America*. Servier submits, first, that the arguments of the United States arose under a specific

[redacted]

189. Poland contends that it is not sufficient for an investor to show a simple causal link between the impugned measure and an investment; there must be proximity, such that the measures directly touch and concern the relevant investments.[300] This, Poland argues, is confirmed by the jurisdictional clause in Article 8 of the Treaty that refers to "[a]ny dispute *relating to investments* between one Contracting Party and an investor of the other Contracting Party..."[301] Poland rejects Servier's argument that Article 8(2)'s reference to "disputes relating to the dispossession measures referred to in Article 5, paragraph 2" requires only a nexus between the dispute and the measures complained of.[302] According to Poland, the real question is whether there is a sufficient nexus between Poland's non-renewal decisions and the Claimed Investments, not between Poland's non-renewal decisions and the investor.[303]

190. Thus, according to Poland, the measures at issue here are Poland's decisions not to renew marketing authorisations for Detralex and Eurespal Syrup, taken in the "normal course of [Poland's] duties as pharmaceutical regulator," and based on the drugs' failure to comply with EU law requirements.[304] Servier has not pleaded that the marketing authorisations are a protected investment; Servier has pleaded that [redacted]

NAFTA provision that has no counterpart in this case. Second, the facts of *Methanex* are inapposite, because the measures at issue there did not refer to the actual product produced by the claimant (methanol), but rather to a product called MTBE; thus, no nexus existed between the impugned measures and the claimant. By contrast, the measures at issue in this arbitration specifically concern Servier's products. Claimants' First Post-Hearing Submission, paras. 118-119; *see also* Reply, para. 200.

298 Statement of Defence, para. 376.

299 Statement of Defence, para. 376.

300 Statement of Defence, paras. 377-382; Rejoinder, para. 200.

301 Statement of Defence, para. 378; Respondent's Second Post-Hearing Brief, para. 5 (Poland's emphasis).

302 Rejoinder, para. 201; Reply, paras. 197-198.

303 Rejoinder, para. 202.

304 Statement of Defence, para. 383; Respondent's First Post-Hearing Brief, para. 13.

305 Statement of Defence, paras. 383-384; Rejoinder, para. 203.

[redacted]

192. Contrary to Servier's allegations, Poland states that it is not seeking to read indirect expropriation out of the Treaty. It concedes that Article 5(2) provides that both direct and indirect expropriation are prohibited except in certain circumstances. However, Poland submits, this does not mean that there is no need to show a legally sufficient connection between the measures and the investment as provided in Article 8(1). The word "indirect" merely recognises that an investor's title need not be directly interfered with; it does not relate to the required nexus.[309]

(6) Location of the Investment; cross-border sale of goods

Servier's Arguments

[redacted]

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306 Statement of Defence, paras. 384-387; *see also* Rejoinder, para 203; Respondent's First Post-Hearing Brief, para. 13; Respondent's Second Post-Hearing Brief, para. 6.

307 Rejoinder, para. 203.

308 Statement of Defence, para. 388.

309 Rejoinder, para. 204.

310 Reply, paras. 178, 192; Claimants' First Post-Hearing Submission, para. 116.

[redacted]

311 Reply, paras. 179-186, 188.

312 Reply, para. 180; Claimants' First Post-Hearing Submission, para. 111.

313 Reply, para. 181.

314 Reply, para. 182.

315 Reply, paras. 182-184; Claimants' First Post-Hearing Submission, para. 111.

316 Reply, paras. 186-187, n.180, 181; Claimants' First Post-Hearing Submission, para. 110[redacted]

317 Reply, para. 185.

[redacted]

198. In addition, Servier contends that, under the Pharmaceutical Law, separate authorisations from the Polish government are required for the manufacturing and the import of medicinal products.[319] [redacted]

202. Finally, Servier disputes on several bases Poland's reliance on *ADM v. Mexico*. First, in that case, the local company was a joint venture between the two claimants, who were not part of the same group of companies. Second, the case concerned a commodity good (high fructose corn syrup), rather than a branded product. Third, in that case, the Tribunal did award damages to the local company, including lost profits; the only damages not awarded were those claimed for lost sales of high fructose corn syrup produced outside the territory of Mexico. By contrast, no sales outside Poland are at issue. Finally, *ADM* does not represent

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318 Reply, para. 188.

319 Reply, para. 189.

320 Reply, paras. 189-190 (citing Exhibit C-177 and Exhibits R-164 and 163).

321 Claimants' First Post-Hearing Submission, para. 112.

322 Reply, paras. 193-194.

323 Claimants' First Post-Hearing Submission, para. 113.

jurisprudence constante, since the Tribunal in the subsequent case of *Cargill v. Mexico* reached a different result on similar facts.[324]

Poland's Arguments

[redacted]

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[324] Claimants' First Post-Hearing Submission, paras. 114-115.

[325] Statement of Defence, para. 391.

[326] Statement of Defence, paras. 391-402, 405; Rejoinder, paras. 193, 196.

[327] Statement of Defence, para. 391; Rejoinder, paras. 191-195; Respondent's First Post-Hearing Brief, para. 107.

[328] Statement of Defence, paras. 394, 397 (citing Exhibits R-163 and 164).

[329] Statement of Defence, para. 394; Respondent's First Post-Hearing Brief, para. 108.

[330] Respondent's First Post-Hearing Brief, para. 108.

[331] Respondent's First Post-Hearing Brief, para. 108.

[redacted]

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[332] Statement of Defence, para. 395 (citing Exhibit C-8).

[333] Statement of Defence, para. 398.

[334] Statement of Defence, para. 396.

[335] Statement of Defence, para. 399.

[336] Respondent's First Post-Hearing Brief, para. 108.

[337] Statement of Defence, paras. 403-404.

[338] Statement of Defence, para. 405.

[redacted] In so arguing, Poland relies on *ADM v. Mexico*[341] for the proposition that, even where certain activities are carried out in the host State, the Tribunal must analyse whether the claimed losses relate to investments made within the host State. In that case, the Tribunal refused to award damages for lost profits on high fructose corn syrup the Claimants would have produced in the United States and exported to their subsidiary in Mexico but for the tax at issue.[342] Similarly, here, the presence of Servier subsidiaries in Poland does not entitle Servier to recover. Rather, to assess its jurisdiction, the Tribunal must determine the "exact losses" sought to be recovered, and whether they are attributable to investments in Poland.[343]

(7) Servier's Additional Claims

Servier's Arguments

207. According to Servier, this Tribunal has jurisdiction under Article 8(2) to hear and decide disputes relating to the dispossession measures referred to in Article 5(2) of the Treaty. Servier further submits that:

> [i]t is equally apparent that, under paragraph 3 of Article 8, this Tribunal must, in deciding this dispute, apply "the provisions of this Agreement and the rules and principles of international law." It is beyond contest that "the provisions of this Agreement" include Articles 3, 4 and 5 of that Agreement, which include requirements of fair and equitable treatment, national treatment and full protection and security, among others.[344]

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339 Statement of Defence, para. 406.

340 Respondent's First Post-Hearing Brief, para. 109.

341 *Archer Daniels Midland Co. and Tate & Lyle Ingredients Americas, Inc. v. United Mexican States*, ICSID Case No. ARB (AF)/04/5, Award dated 21 Nov. 2007.

342 Respondent's First Post-Hearing Brief, para. 109.

343 Respondent's First Post-Hearing Brief, para. 110.

344 Reply, para. 363; *see also* Servier's letter to the Tribunal dated 2 Aug. 2010, p. 2 and Servier's letter to the Tribunal dated 28 July 2010, pp. 2-3.

208. Servier rejects Poland's allegation that the applicable law clause issue is one of jurisdiction that was disposed of in the Tribunal's Interim Award on Jurisdiction. Rather, it says, the Tribunal deferred the question to the merits phase of these proceedings.[345]

209. Servier submits that Article 8(3) of the Treaty, along with Article 33(1) of the UNCITRAL Rules, sets out the applicable law that the Tribunal must apply to the substance of the dispute.[346] According to Servier, the Treaty clearly provides that the applicable law to this case includes all of the provisions of the Treaty—including those on fair and equitable treatment, national treatment, and full protection and security—and international law.[347] Servier claims that Poland's interpretation of Article 8(3) renders ineffective that Article's express reference to the "provisions" of the Treaty.[348]

Poland's Arguments

210. It is Poland's position that the Claimants' Additional Claims fall outside of Poland's consent to arbitration as defined by Article 8 of the Treaty.[349]

211. Poland argues that the Applicable Law Clause does not expand this Tribunal's jurisdiction to the Claimants' Additional Claims. Article 8(2) limits the Tribunal's jurisdiction to disputes relating to expropriation under Article 5(2) of the Treaty. Article 8(3) provides that in exercising jurisdiction and considering the claims relating to such disputes, the Tribunal shall rule in accordance with the other provisions of the Treaty and the rules of international law.[350] Poland submits that Servier's interpretation is untenable because it would mean that an investor who could make an allegation of expropriation sufficient for a tribunal to accept

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345 Reply, paras. 359-361; *see also* Tribunal's Decision on Poland's Application for Bifurcation dated 27 Aug. 2010, p. 3; Interim Award on Jurisdiction dated 3 Dec. 2010, para. 15: "[T]he Parties' arguments concerning the effect of the applicable law dispositions in Article 8(3) of the Treaty would not be determined in a preliminary bifurcated phase, but would be addressed in the merits phase of these proceedings."

346 Reply, para. 362; *see also* Statement of Claim, paras. 267-268.

347 Reply, paras. 366-367, 369; *see also* Statement of Claim, paras. 269-270.

348 Reply, para. 368.

349 Statement of Defence, paras. 408, 419.

350 Statement of Defence, paras. 420-421. Poland also asserts that Servier's position in this respect has "changed repeatedly" over the course of the proceedings. Poland objects to Servier's latest position (as of 23 December 2010) on this point as set out in its Reply to Poland's First Submission on Objections to Jurisdiction dated 28 Sept. 2010. Poland submits that the arguments contained therein were not made in a timely manner and therefore should not be entertained at this stage (*see* Statement of Defence, paras. 413-418).

jurisdiction could then also bring claims for breach of other provisions of the treaty and any other applicable rule of international law.[351]

212. Poland notes that the Inter-State Dispute Clause of the Treaty—Article 11—contains no restriction on the subject matter of disputes but contains an identical applicable law clause. It asserts that it could not have been the Contracting Parties' intention that the two identical applicable law clauses would mean that the very differently drafted Articles 8 and 11 would have the same effect and scope.[352]

213. Poland also describes Servier's argument regarding the effect of the Applicable Law Clause as unprecedented in investment treaty arbitration.[353]

214. Finally, Poland claims that Servier's approach to this issue should have costs implications, on the grounds that: (1) its argument is manifestly flawed; (2) it has repeatedly changed its position; and (3) it resisted Poland's attempt to address this issue as a preliminary matter, resulting in wasted time and costs.[354]

B. MERITS

1. Servier's Expropriation Claim – Dispossession under Article 5(2) of the Treaty

215. Servier claims that Poland's "revocation" of the marketing authorisations for Detralex and Eurespal Syrup has had "the effect of dispossessing [Servier], either directly or indirectly, of investments belonging to" it, in violation of Article 5(2) of the Treaty.[355]

(1) Legal test for indirect expropriation under Article 5(2) of the Treaty

216. The Parties differ as to the correct test for indirect expropriation under Article 5(2) of the Treaty.

Servier's Arguments

217. Servier asserts that under customary international law, the expropriation of an investment can only take place for a public purpose, in a non-discriminatory manner, and against compensation.[356]

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[351] Statement of Defence, paras. 422-423.

[352] Statement of Defence, para. 424.

[353] Statement of Defence, paras. 425-429.

[354] Statement of Defence, para. 431. *See* above n. 350.

[355] Statement of Claim, paras. 195, 187, 212; Reply, paras. 204, 207.

[356] Statement of Claim, para. 197.

218. Servier contends that Article 5(2) of the Treaty provides a broader treaty standard than customary international law because Article 5(2) refers to "any other measures which would have the effect of dispossessing investors".[357] Servier claims that this shows that the Contracting Parties intentionally adopted a broader standard than that which exists under customary international law,[358] and that they intended to grant investors the widest possible protection against measures regardless of the grounds for the measures.[359]

219. According to Servier, "dispossession" is defined as "deprivation of [...] rightful use of property" and does not require any loss or transfer of title.[360] Because the Treaty requires that measures have the *effect* of dispossessing the investor of its investment, it is the *effect* of the measure, not the physical transfer of title to the investment, which determines whether it is expropriatory or not.[361] As such, Servier contests Poland's assertion that to amount to indirect expropriation, the investor must be deprived of its fundamental rights of ownership and/or control over the investment.[362] That, it says, runs counter to the general consensus among tribunals that an expropriation can occur without a transfer of title.[363]

220. Servier submits that the "key question" or "main criteria" in deciding whether an indirect expropriation has taken place under Article 5(2) of the Treaty is the effect of the State's measures upon the economic benefit and value of the investment: "Whenever this effect is substantial and lasts for a significant period of time or is by its nature unlimited in time, it will be established *prima facie* that an appropriation of the property has occurred."[364] In other words, "indirect expropriation only requires a 'substantial' deprivation ... or that the challenged measure deprive the investor 'in whole or in significant part, of the use or reasonably-to-be-expected economic benefit' of its investment." Thus, a total loss in value, as suggested by Poland, is not required.[365] In support of this contention, Servier cites several

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357 Statement of Claim, para 200.

358 Statement of Claim, para. 198.

359 Statement of Claim, para. 200.

360 Statement of Claim, para. 199.

361 Reply, paras. 209, 211.

362 Reply, paras. 212-214; *see also* Claimants' Second Post-Hearing Submission, paras. 26-27. For Poland's characterisation of the Parties' disagreement on this point, *see* Rejoinder, para. 216(i).

363 Reply, paras. 214, 221-226.

364 Statement of Claim, para. 202; Reply, paras. 216-217; *see also* Claimants' Second Post-Hearing Submission, para. 11.

365 Claimants' Second Post-Hearing Submission, para. 11.

cases which it says involve the impact of State measures on [redacted] in the context of treaty language similar to Article 5(2).[366]

221. Poland asserts that the test to be applied to a case of expropriation includes multiple elements (*see infra* para. 227 *et seq.*). One of the elements of the test put forward by Poland is that any interference by a measure with an investment must ordinarily be permanent or irreversible (*see infra* para. 229). In response to this, Servier contends that what is relevant here is not whether the measure can later be undone, but rather what the nature of the measure is.[367] State responsibility arises at the time when an act, which is attributable to the State and which constitutes an international wrong, takes place.[368]

222. In response to Poland's argument that a proper examination of a claim for expropriation begins with a consideration of the vested rights of the investor, and that Servier's Claimed Investments are not legal rights protected by Polish law (*see supra* para. 131), Servier reiterates that it is the Treaty, not Polish law, that is relevant in assessing whether Servier's assets are protected investments.[369]

223. Servier notes Poland's inclusion as an additional factor in the test for indirect expropriation of "the extent to which the measures have the effect that the host State or preferred third parties obtain the benefit of the claimant's investment." Servier argues that neither the Treaty nor customary international law require that a State or a "preferred third party" benefit from the expropriated assets. Indirect expropriation can occur even if it is not to the benefit of the host State.[370]

224. Servier also notes Poland's inclusion in the test of an assessment as to whether the measure would defeat the legitimate expectations of the investor created through prior conduct of the State.[371] Servier argues that (1) no reliance on a State's prior representations or conduct need to be established to demonstrate the expropriatory nature of a State measure;[372] and (2) even if one assumed otherwise, numerous investments are made without reliance on specific

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366 Statement of Claim, paras. 203-206.

367 Reply, para. 251.

368 Reply, para. 251.

369 Reply, para. 218.

370 Reply, paras. 267-269; Statement of Claim, para. 211.

371 Reply, para. 272.

372 Reply, paras. 273-274.

representations or conduct by the State, but are based rather on a State's duty to act lawfully.[373]

Poland's Arguments

225. Poland asserts that Servier's legal test for expropriation cannot be reconciled with the ordinary meaning of the Treaty text. The use of the terms "dépossession" (loss of control) and "pozbawienia własności" (deprivation of ownership) in the French and Polish versions of the Treaty respectively imply that a severe degree of interference with control of the investment is required.[374]

226. Further, the use of Treaty language which specifically refers to control (in French) and ownership (in Polish) when describing indirect expropriation also supports the view that a loss of value, on its own, is not sufficient to establish a breach of Article 5(2).[375] In other provisions of the Treaty, the drafters specifically referred to losses by using the terms "pertes" in French and "strat" in Polish. Those terms are absent from Article 5(2). Thus, Poland argues, that the terms "dépossession" and "pozbawienia własności", connote something distinct from, and more severe than, pure economic loss.[376]

227. Poland submits that a substantial diminution in the value of an investment alone does not suffice to demonstrate an indirect expropriation under Article 5(2);[377] a proper analysis must take into account a range of additional factors (discussed below).[378] Poland contends that Servier's test is not supported by prior authorities on indirect expropriation; tribunals in such cases have consistently endorsed multi-factor tests and have not treated the economic effects of a measure as dispositive.[379]

228. As a practical matter, Poland argues that the effect of regulatory measures on the value of an investment will often depend on complex interactions with specific economic variables. Servier's test, Poland argues, would make a State's liability for expropriation dependent on factors outside of its knowledge or control.[380]

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[373] Reply, paras. 275-276.

[374] Statement of Defence, para. 449; Rejoinder, para. 219.

[375] Rejoinder, para. 220; *see also* Respondent's Second Post-Hearing Brief, para. 8.

[376] Statement of Defence, para. 439 (citing Articles 5(3) and 6(1)(e) of the Treaty where the drafters specifically refer to "losses" sustained by investments); Rejoinder, para. 220.

[377] Rejoinder, paras. 223-225, and Appendix 1; Statement of Defence, paras. 440(i)-(iii).

[378] Statement of Defence, paras. 435(i), 438.

[379] Statement of Defence, paras. 440(i)-(iii); *see also* Rejoinder, paras. 223-225 and Appendix 1.

[380] Statement of Defence, para. 441.

229. Poland maintains that the correct assessment of whether a measure has indirectly "dispossessed" an investor of its investment under Article 5(2) requires an examination of the following factors:

(a) the nature of the rights of the investor: a claimant must establish that it has a vested right that is protected as a matter of national law and under the Treaty, to the allegedly expropriated asset;[381]

(b) the degree of interference with the investment: whether the State party's interference with the rights amounts to a dispossession. In this regard, Poland submits that past tribunals have considered (1) whether the investor has been deprived of its fundamental rights of ownership and/or control over the investment; (2) the consequential loss in the value of an investment; and (3) whether the interference is permanent and irreversible.[382]

(c) the significance of the character of the measures involved: if a measure can be characterised as involving a good faith exercise of regulatory powers, in the sense of promoting a public purpose in a non-discriminatory and proportional manner, it cannot be treated as giving rise to a dispossession (*see infra* section 2);[383] and,

(d) other relevant factors: (1) the extent to which the measures at issue have the effect that the host State or preferred third parties obtain the benefit of the claimant's investment; and (2) whether those measures defeat the legitimate expectations of the investors created through the prior conduct of the State.[384]

230. In sum, Poland submits that Servier must prove that its decision not to renew the marketing authorisations for Detralex and Eurespal Syrup "interfered with the Claimed Investments such that they resulted in a permanent and irreversible deprivation or elimination of [Servier's] control over, as well as the entire value of," Servier's investments; that the measures did not constitute a valid exercise of Poland's regulatory powers; and that Article 5(2) of the Treaty was breached notwithstanding Poland's compliance with Servier'

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381 Statement of Defence, paras. 447-448; Rejoinder, para. 213.

382 Statement of Defence, paras. 449-450; *see also* Respondent's First Post-Hearing Brief, para. 20.

383 Statement of Defence, para. 451; Rejoinder, paras. 211(ii), 259 *et seq.*

384 Statement of Defence, paras. 452-454, 542 (on benefit to others); 543 (on legitimate expectations); Rejoinder, paras. 211(iii), 342 *et seq.*

legitimate expectations, the absence of benefit to Poland, and that Poland's actions were taken pursuant to the EU Treaty, which both Poland and France have ratified.[385]

(2) Application of the legal test for indirect expropriation under Article 5(2) of the Treaty

(a) Whether Servier has established that it has vested rights with respect to the Claimed Investments

Servier's Arguments

231. Servier's submissions on its alleged vested rights with respect to the Claimed Investments are summarised above in Section A.1(3).

Poland's Arguments

232. It is Poland's position that Servier has failed to establish that, as a matter of Polish law, it has protected rights over the majority of the Claimed Investments other than [redacted]

(b) Whether Servier retains title to and control over the Claimed Investments; whether Poland's Measures have interfered with any of Servier's rights in the Claimed Investments

[redacted]

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385 Respondent's First Post-Hearing Brief, para. 20; Statement of Defense, paras. 438 *et seq.*; *see also* Respondent's Second Post-Hearing Brief, para. 8 (arguing that Poland's measures cannot be deemed expropriatory in the absence of (1) a loss of control over, or interference with, rights protected under Polish law; (2) any defeat of Servier's legitimate expectations; and (3) any transfer of economic benefits to Poland).

386 Statement of Defence, paras. 456-457; Rejoinder, para. 213; *see also supra* paras. 141 *et seq.*

387 Rejoinder, para. 258.

388 Claimants' Second Post-Hearing Submission, para. 25.

389 Reply, para. 220.

[redacted]

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390 Statement of Claim, para. 209.

391 Reply, para. 227.

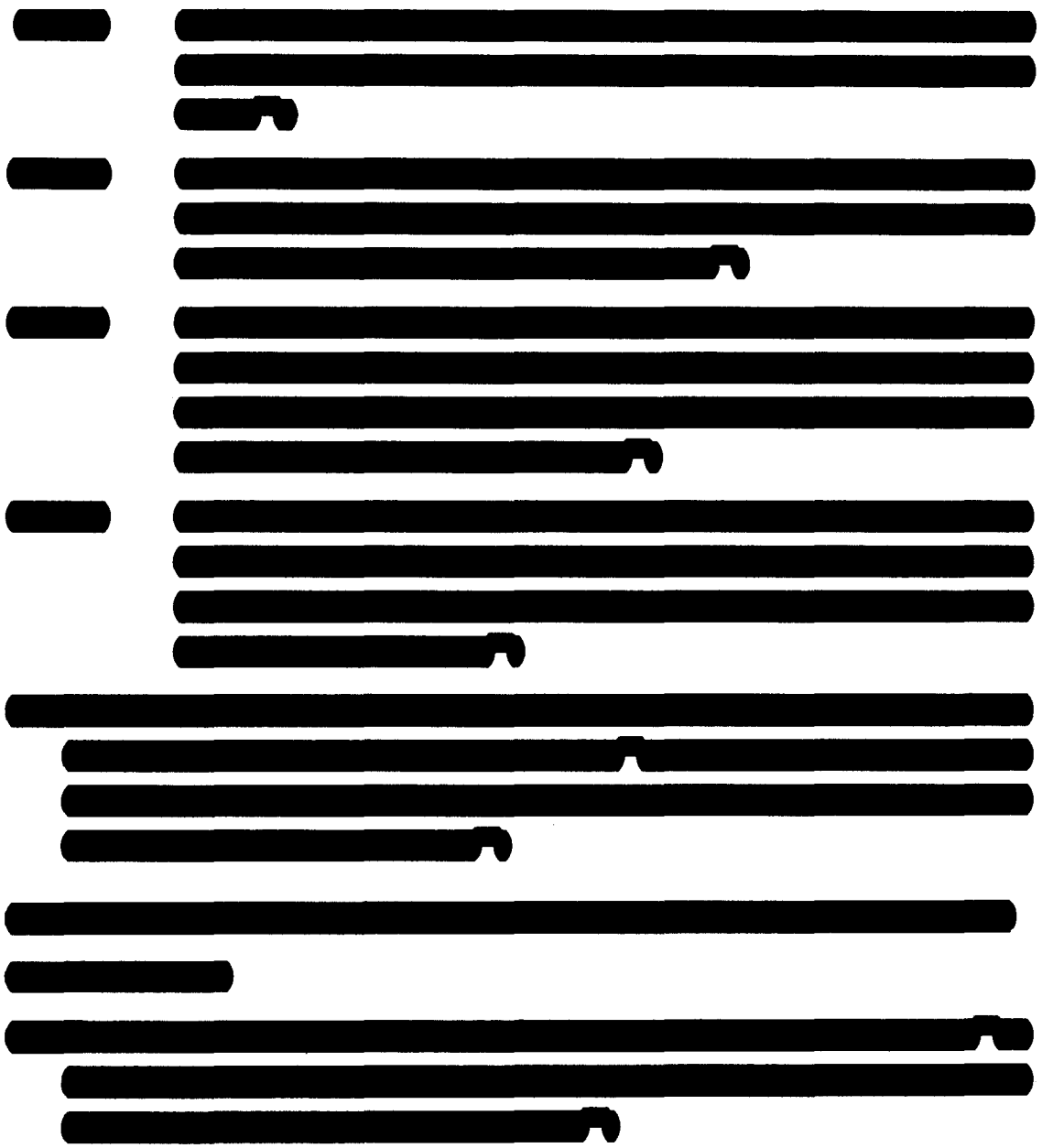
392 Reply, para. 228.

393 Statement of Claim, para. 208.

394 Statement of Claim, para. 208.

395 Reply, para. 229; Statement of Claim, para. 208.

396 Statement of Defence, paras. 458-459, 461-462; Rejoinder, para. 228.



[397] Statement of Defence, para. 460(i); Rejoinder, para. 228(i).

[398] Statement of Defence, para. 460(ii) Rejoinder, para. 228(ii).

[399] Statement of Defence, para. 460(iii); Rejoinder, para. 228(iv).

[400] Statement of Defence, para. 460(iv); Rejoinder, para. 228(iii).

[401] Rejoinder, para. 227.

[402] Respondent's First Post-Hearing Brief, para. 35.

[403] Reply, para. 231; Claimants' Second Post-Hearing Submission, para. 12.

[404] Claimants' Second Post-Hearing Submission, para. 12.

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405 Reply, paras. 232-233.

406 Reply, para. 234; Claimants' Second Post-Hearing Submission, para. 12.

407 Reply, paras. 234-235.

408 Reply, para. 236.

409 Reply, para. 239.

410 Reply, paras. 241-242.

[411] Reply, paras. 243-244.

[412] Claimants' First Post-Hearing Submission, para. 7; Claimants' Second Post-Hearing Submission, para. 12.

[413] Reply, para. 246; Claimants' First Post-Hearing Submission, para. 4. *See* Reply, paras. 245-249 for Servier's claimed sales figures since the marketing authorisations came into effect.

[414] Claimants' First Post-Hearing Submission, para. 5.

[415] Claimants' First Post-Hearing Submission, para. 4.

[416] Claimants' First Post-Hearing Submission, para. 8.

[redacted]

Poland's Arguments

244. Poland contends that Servier has failed to support its contention that Poland's Measures have "indisputably destroyed the value of Servier's investments in Detralex and Eurespal Syrup."[418] [redacted]

[417] Claimants' First Post-Hearing Submission, para. 9.

[418] Statement of Defence, para. 466 (quoting Statement of Claim, para. 207); Respondent's First Post-Hearing Brief, para. 21.

[419] Statement of Defence, para. 466; *see also* Respondent's Second Post-Hearing Brief, para. 9.

[420] Rejoinder, paras. 242-246.

[421] Statement of Defence, paras. 467-468.

[422] Rejoinder, para. 247; Respondent's First Post-Hearing Brief, paras. 23-24; Respondent's Second Post-Hearing Brief, para. 15.

[423] Statement of Defence, para. 471.

[424] Rejoinder, paras. 248-249; Respondent's First Post-Hearing Brief, para. 22; Respondent's Second Post-Hearing Brief, para. 12. [redacted]

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[redacted] [redacted]

[redacted]

425 Respondent's First Post-Hearing Brief, para. 22.

426 Statement of Defence, para. 472; Rejoinder, para. 249.

427 Rejoinder, para. 250.

428 Respondent's Second Post-Hearing Brief, para. 14 (referring to Exhibit C-221, Second Witness Statement of [redacted]).

429 Respondent's Second Post-Hearing Brief, para. 14.

430 Respondent's First Post-Hearing Brief, para. 25.

431 Respondent's Second Post-Hearing Brief, para. 18.

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[432] Statement of Defence, para. 473; Rejoinder, paras. 256-258; Respondent's Second Post-Hearing Brief, paras. 16-17.

[433] Respondent's Second Post-Hearing Brief, para. 17.

[434] Statement of Defence, para. 474; Rejoinder, para. 251.

[435] Statement of Defence, para. 475.[redacted]

[436] Statement of Defence, para. 476; Rejoinder, para. 252.

[437] Statement of Defence, para. 477; Rejoinder, paras. 253-255.

(d) Whether Servier can establish that a future deprivation of value is inevitable, irreversible, or would be permanent

Servier's Arguments

247. Servier reiterates that, as of 31 December 2008, it was no longer able to sell new batches of Detralex and Eurespal Syrup in Poland, and that remaining supplies are non-existent for Detralex and limited for Eurespal Syrup.[438]

248. According to Servier, the record clearly shows that Poland's measures are permanent and irreversible.[439] [redacted]

249. According to Servier, the Administrative Court in Warsaw has expressly ruled that Poland's refusal to renew the marketing authorisation for Detralex is permanent and irrevocable. Any renewal of the Detralex marketing authorisation must have occurred on or before 31 December 2008.[442] Servier submits that the reasoning of the Warsaw Court would require an identical conclusion with respect to the Ministry's refusal of harmonisation of Eurespal Syrup.[443]

[redacted]

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[438] Reply, para. 246; Claimants' First Post-Hearing Submission, paras. 4-5. *See also* Reply, paras. 245-249 (setting out Servier's alleged sales figures since the marketing authorisations came into effect). Servier denies that it was permitted to market Detralex for six months following the expiry of its marketing authorisation as suggested by Poland at para. 222 of its Statement of Defence. Claimants' First Post-Hearing Submission, para. 4.

[439] Claimants' Second Post-Hearing Submission, para. 13.

[440] Reply, para. 250.

[441] Claimants' Second Post-Hearing Submission, paras. 15-16.

[442] Reply, paras. 253-254 (referring to Exhibit C-135 Judgment of the Regional Court of Warsaw dated 6 Dec. 2010, pp. 17-18); *see also* Claimants' Second Post-Hearing Submission, para. 23.

[443] Reply, para. 254.

[444] Reply, paras. 257-258.

[redacted]

[redacted]

[redacted]

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445 Claimants' Second Post-Hearing Submission, para. 16. [redacted]
Claimants' Second Post-Hearing Submission, paras. 17-18.

446 Claimants' First Post-Hearing Submission, para. 16; Reply, para. 259.

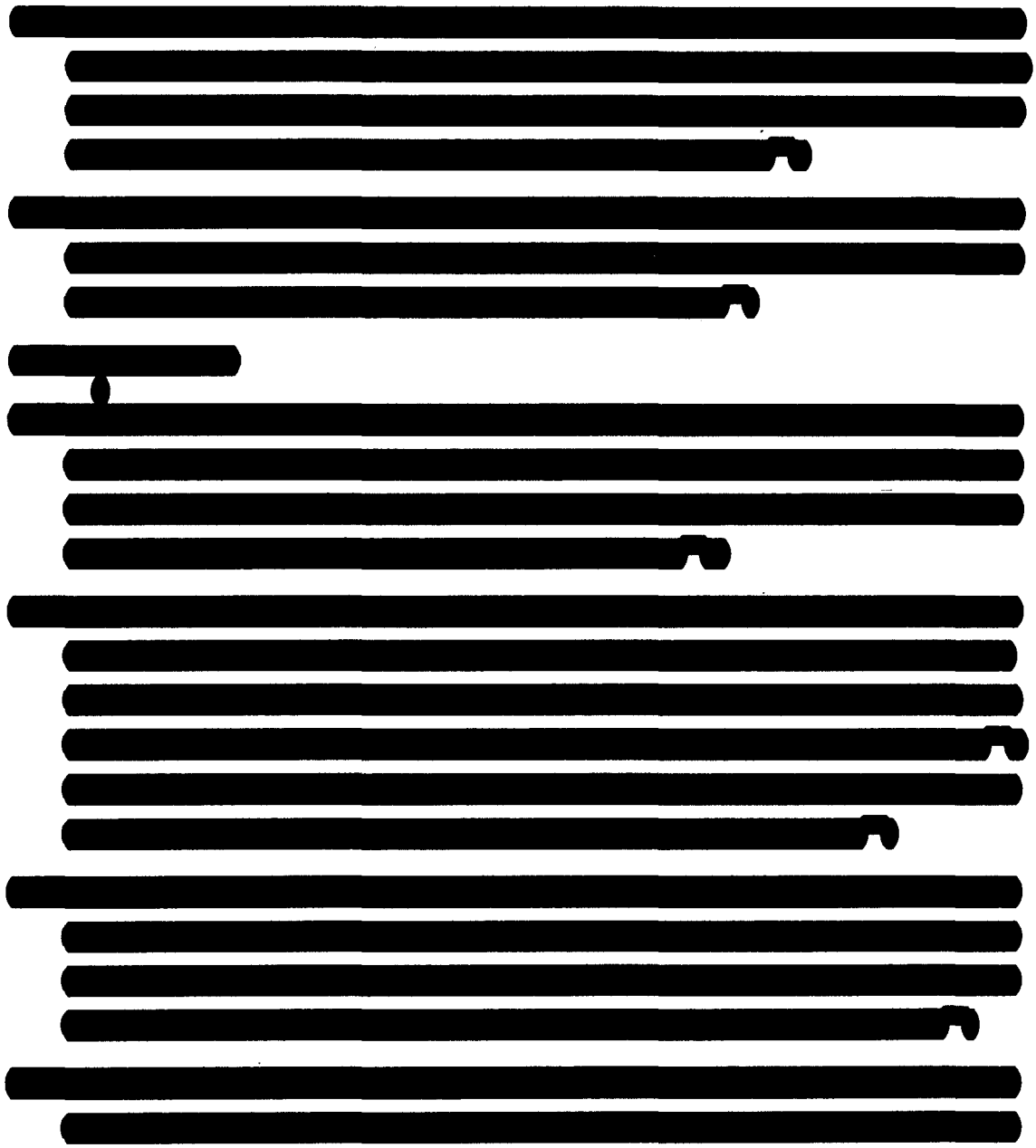
447 Reply, para. 260; *see also* Claimants' Second Post-Hearing Submission, para. 19.

448 Claimants' First Post-Hearing Submission, paras. 15, 17.

449 Claimants' Second Post-Hearing Submission, para. 20.

450 Claimants' First Post-Hearing Submission, paras. 11-12.

451 Claimants' First Post-Hearing Submission, paras. 13-14.



[452] Claimants' Second Post-Hearing Submission, para. 21.

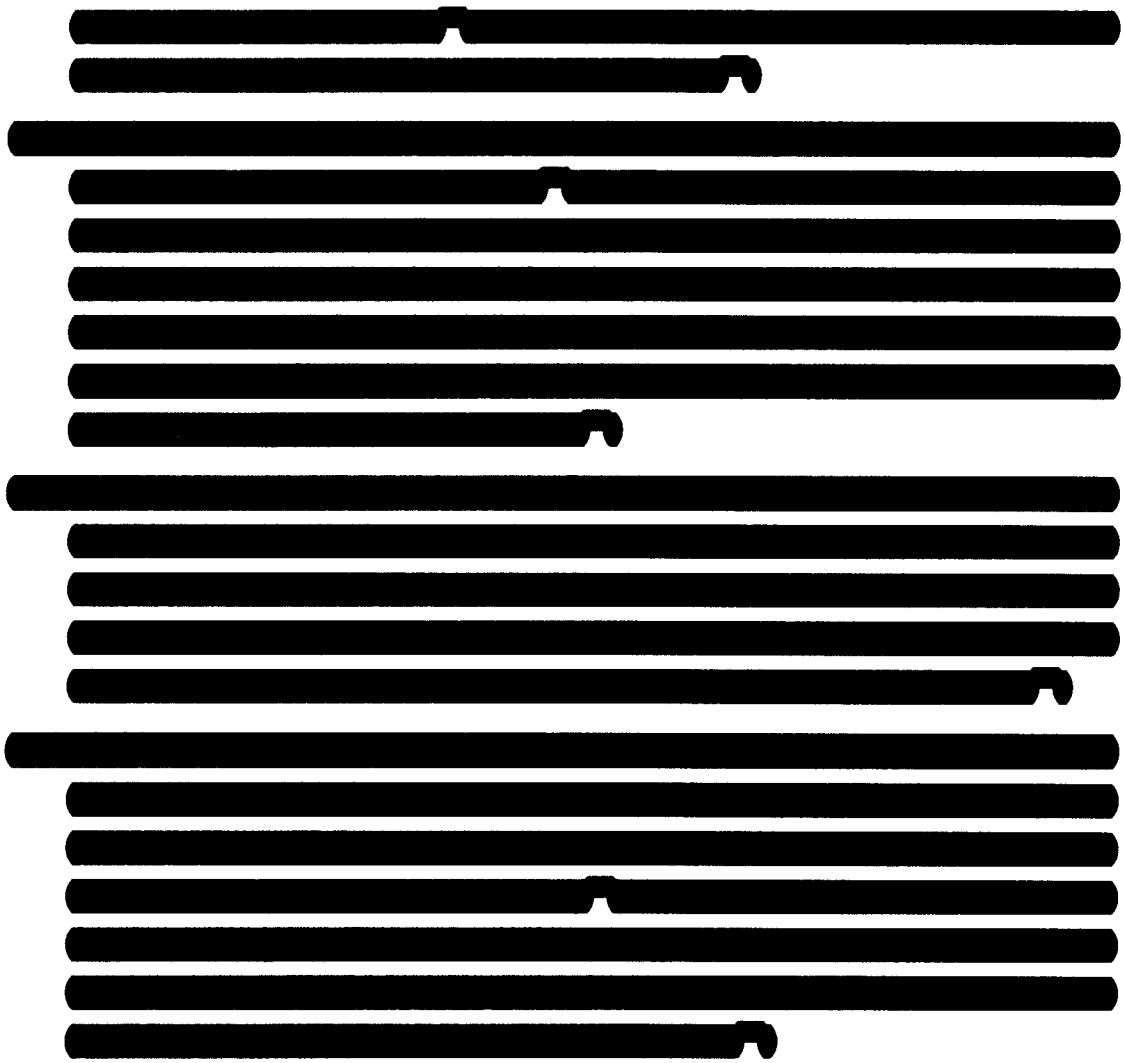
[453] Claimants' First Post-Hearing Submission, para. 17; *see also* Claimants' Second Post-Hearing Submission, para. 21.

[454] Statement of Defence, para. 484; Rejoinder, paras. 230, 234, 238; Respondent's First Post-Hearing Brief, para. 26; Respondent's Second Post Hearing Brief, para. 19.

[455] Rejoinder, para. 232.

[456] Rejoinder, para. 233.

[457] Respondent's First Post-Hearing Brief, para. 27; Respondent's Second Post-Hearing Brief, para. 19.



262. Poland also adopts the view that because Servier continues to sell Detralex and Eurespal Syrup, its case is built on a future loss in value. It is not inevitable, however, that Servier

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458 Rejoinder, paras. 236-237; Respondent's First Post-Hearing Brief, para. 28.

459 Respondent's First Post-Hearing Brief, para. 28; Respondent's Second Post-Hearing Brief, paras. 20-21.

460 Respondent's First Post-Hearing Brief, para. 29. Respondent's First Post-Hearing Brief, para. 30.

461 Respondent's First Post-Hearing Brief, para. 31; *see also* Respondent's Post-Hearing Brief, para. 22.

462 Respondent's First Post-Hearing Brief, para. 32; Respondent's Second Post-Hearing Brief, para. 19.

463 Rejoinder, paras. 239-241.

464 Respondent's First Post-Hearing Brief, para. 33.

will incur these losses or that they will be permanent.[465] On this point, Poland also alludes to the compensation measures available under the Treaty, under which compensation is to be determined before the date of dispossession and paid without delay. In Poland's view, Servier seeks to be paid for losses which may not occur and which may be neutralised at a later point in time.[466]

[redacted]

(e) The significance of whether the impugned Measures are taken pursuant to an EU Treaty which Poland and France have ratified

Servier's Arguments

264. Servier rejects Poland's argument that Poland's Measures "are, in broad terms, the product of *a joint* French and Polish policy choice," expressed in the EU Treaty.[468] In Servier's view, it is absurd to suggest that, because France and Poland are members of the EU, each and every action they take is mandated by their obligations under the EU Treaty or coordinated by them. Servier adds that neither the EU Treaty, nor the EU Pharmaceuticals Directive, requires Poland to favour the local pharmaceutical industry and adopt measures to drive foreign competitors from the market; to the contrary, it disfavours such conduct.[469]

Poland's Arguments

265. Poland refers to Article 31(3)(c) of the Vienna Convention on the Law of Treaties[470] ("Vienna Convention"), which provides that in interpreting a treaty, "any relevant rules of international law applicable in the relations between the parties...shall be taken into account, together with the context". [redacted]

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[465] Statement of Defence, para. 483.

[466] Statement of Defence, para. 485.

[467] Respondent's First Post-Hearing Brief, para. 34.

[468] Reply, para. 265 (quoting Statement of Defence, para. 538) (emphasis in the original).

[469] Reply, paras. 265-266.

[470] Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331.

That Directive was adopted pursuant to the EU Treaty, which both Poland and France have ratified subsequent to the Bilateral Investment Treaty at issue. Thus, the regulatory requirements imposed by Poland are, in broad terms, the product of a joint French and Polish policy choice; the harmonisation process was concerned with ensuring compliance with EU standards as set out in the EU Pharmaceutical Directive.[471] Poland avers that it would be inappropriate to find that the regulatory requirements which both parties agreed to could give rise to an obligation of compensation.[472]

(f) Whether the benefits of the Claimed Investments have been appropriated by Poland or transferred to other entities

Servier's Arguments

266. According to Servier, it is irrelevant whether Poland intended to effect an expropriation or whether the State itself benefited from the taking to a finding of indirect expropriation. Having said that, Servier asserts that "Polish authorities have 'taken away' Servier's investments and given them to Servier's Polish competitors."[473]

267. Servier states that Poland viewed the harmonisation process as a means to promote the local pharmaceutical industry, in particular through the registration of low-cost local generic products.[474] Indeed, Servier argues, Poland's measures have benefited local Polish companies, by transferring clientele for Detralex and Eurespal Syrup to Servier's Polish competitors. In the absence of Detralex, doctors and patients have turned to Diosminex and Pelethrocin. Moreover, because Servier has not been permitted to advertise Eurespal Syrup, most doctors and patients are no longer aware of its availability and Polish generics have succeeded in positioning themselves as direct substitutes.[475] Servier submits that sales of Diosminex, Pelethrocin, and Eurespal Syrup generics have increased since 2009, at a time when Servier could no longer market Detralex and Eurespal Syrup in Poland. Once sales of Servier's drugs on the market are exhausted, its market share will be definitively taken over by drugs of Polish competitors.[476]

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[471] Statement of Defence, paras. 537-538; Rejoinder, para. 352.

[472] Statement of Defence, para. 539; Rejoinder, para. 351.

[473] Statement of Claim, para. 211.

[474] Reply, para. 271.

[475] Claimants' First Post-Hearing Submission, para. 6.

[476] Reply, para. 271.

Poland's Arguments

268. In response to Servier's argument that Poland has "taken away" Servier's investments and given them to Servier's Polish competitors, Poland contends that [redacted] Nor has Poland itself received any benefit or been enriched in any way by the non-renewal of the marketing authorisations for Detralex and Eurespal Syrup.[477]

269. Poland further argues that, contrary to what Servier submits, the extent to which the benefits of a claimant's investment has been appropriated by a host State or preferred third parties is a factor in expropriation jurisprudence.[478] Furthermore, in Poland's view, the mere fact that there has been a shift in the market shares for Detralex and Eurespal Syrup to their competitors since 2009 does not, by itself, establish that the benefits associated with the Claimed Investments have been appropriated by a third party; any gain in market share does not establish appropriation of the benefits of Servier's alleged [redacted][479]

(g) Whether Servier had a legitimate expectation of being able to market Detralex and Eurespal Syrup indefinitely

Servier's Arguments

270. Servier submits that the Polish authorities did not and do not have the power to grant or refuse an application on the basis of reasons other than those specified in the Polish Pharmaceutical Law. Thus, Servier had the legitimate expectation that Polish authorities would only apply the requirements of the Pharmaceutical Law. Servier claims that Poland applied "unwritten requirements to the Detralex and Eurespal Syrup applications", and thus defeated Servier's legitimate expectations.[480]

271. Poland argues that the fact that Servier's initial investment costs were modest and would have been recouped by now through sales revenue shows that Servier did not rely on an expectation that it would be able to market its products in Poland indefinitely when it first invested. In response, Servier argues that the expectation on the part of an investor to earn a

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[477] Statement of Defence, paras. 540-541.

[478] Rejoinder, para. 349.

[479] Rejoinder, para. 350.

[480] Reply, para. 277.

return and recoup the initial contribution after a certain time is legitimate in the context of investment arbitration.[481]

Poland's Arguments

272. Poland argues that Servier could not have reasonably expected that, by acquiring [redacted] it would enjoy an indefinite authorisation to market its products in Poland.[482]

273. Poland describes Servier's alleged legitimate expectation that Polish authorities would apply the requirements of the Pharmaceutical Law and not "unwritten requirements to the Detralex and Eurespal Syrup applications" as inapposite.[483] Even accepting Servier's argument that the Pharmaceutical Law in itself could serve as a source of its legitimate expectations for the purposes of its indirect expropriation claim. Poland submits that they have not been defeated by Poland's actions. Poland did not apply "unwritten requirements", but complied with applicable domestic laws.[484]

274. Poland points to five factors that it says should have shaped Servier's expectations: (1) the acquisition of [redacted] does not carry with it any permission to sell tangible products; (2) its prior marketing authorisations for Detralex and Eurespal Syrup were finite; (3) the pharmaceutical industry is a highly regulated industry in which regulations continuously evolve in line with scientific advancements and changing levels of risk tolerance; (4) by the time Servier began operations in the Polish market in 1992, it was evident that the Polish regulatory regime for pharmaceuticals would eventually have to comply with EU standards; and (5) Servier received no specific assurances from the Polish government that it would be permitted to market Detralex and Eurespal Syrup indefinitely regardless of compliance with regulatory standards.[485]

[redacted]

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[481] Reply, paras. 278-279.

[482] Statement of Defence, para. 544.

[483] Rejoinder, para. 344.

[484] Rejoinder, para. 345.

[485] Statement of Defence, para. 544; *see also* Rejoinder, paras. 346-347.

[redacted]

2. Poland's exercise of regulatory powers

(1) The legal standard to show the proper use of a State's regulatory powers

276. The Parties agree that, under international law, a State is not liable for dispossession if its actions were a valid exercise of regulatory, or "police," powers.[487]

277. The Parties generally agree on the four elements that must be fulfilled for a measure to constitute an exercise of legitimate regulatory power.[488] The Claimants submit that States must demonstrate that the measure in question was (1) reasonable; (2) non-discriminatory; (3) proportionate to the public interest to be protected; and (4) adopted in good faith.[489] Servier states, additionally, that "[t]hese are not mere factors, but cumulative criteria to establish;" that is, "[a] failing on any one of these cumulative criteria is sufficient to dismiss Poland's affirmative defence."[490] Contrary to Servier's suggestion, Poland argues that "prior authorities have considered these factors 'in combination', with no single factor treated as dispositive."[491]

278. Poland submits that tribunals generally consider (1) the purpose of the measure; (2) whether the measures were discriminatory; (3) the degree of proportionality between the measure and the aim sought to be realised; and (4) whether the measure was taken in good faith.[492] Poland disagrees with the scope of the public purpose test, asserted by Servier, as including additional considerations, such as: (1) a duty to be reasonable; (2) a duty to provide reasons; and (3) the legality of the measure under domestic law. Poland submits that none of these additional conditions are supported by any authority, and that, in any event, Servier's condition of "reasonableness" is essentially the same as the condition of "proportionality".[493] Poland submits that the examination of public purpose does not include these additional

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[486] Statement of Defence, para. 545.

[487] Statement of Claim, para. 213; Statement of Defence, para. 487; Respondent's First Post-Hearing Brief, para. 37.

[488] Statement of Defence, para. 490; Reply, para. 283; Claimants' First Post-Hearing Submission, para. 18.

[489] Statement of Claim, para. 215; Reply, para. 283.

[490] Claimants' First Post-Hearing Submission, para. 19.

[491] Respondent's Second Post-Hearing Brief, para. 24.

[492] Statement of Defence, para. 490.

[493] Rejoinder, paras. 269-271.

considerations; rather, the test is simply whether the public purpose is valid, and whether there was a rational, or plausible, link between the measures and the public purpose.[494]

279. As to the standard of review to be applied by the Tribunal, Poland emphasizes that, in assessing the measures, it "should not embark upon an open-ended enquiry into the scientific correctness of the decisions in question or substitute its own regulatory choices for those made by the competent Polish regulator."[495] Rather, the Tribunal should assess whether the measures were "motivated by honest belief, held in good faith and based on reasonable scientific grounds," that is, whether Poland acted as a reasonable regulator.[496]

(2) Burden of proof

Servier's Arguments

280. Servier argues that Poland has the burden of showing that any justification for the adoption of the disputed Measures complies with the police powers standard. It is an affirmative defence. As such, Servier contends that Poland must make a *prima facie* showing that its Measures fulfil all four criteria of the regulatory powers standard.[497]

Poland's Arguments

281. Poland disputes this. It says that the burden of showing that the Measures do *not* involve a valid exercise of regulatory power remains on Servier; it is not an affirmative defence. Poland is under a duty to identify the regulatory purpose of the Measures and establish that its Measures are reasonably related to that purpose.[498]

282. It also submits that the assessment of whether Poland's Measures can be characterised as non-compensable regulatory actions should not be conflated with an enquiry into their correctness.[499] A deferential standard of review must be employed by the Tribunal when it comes to regulatory decisions based around science and national regulation.[500] According to

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494 Respondent's First Post-Hearing Brief, para. 39.

495 Respondent's First Post-Hearing Brief, para. 38.

496 Respondent's First Post-Hearing Brief, para. 38 (quoting *Methanex Corp. v. United States of America*, NAFTA/UNCITRAL, Final Award dated 3 Aug. 2005, para. 102).

497 Statement of Claim, para. 214; Reply, paras. 284-285; Claimants' Second Post-Hearing Submission, para. 29.

498 Statement of Defence, para. 491; Rejoinder, paras. 261-262; Respondent's Second Post-Hearing Brief, para. 23.

499 Statement of Defence, paras. 492, 502, 525; Rejoinder, para. 263.

500 Rejoinder, paras. 265-267.

Poland, Servier seemed to have accepted this standard of review in its first post-hearing submission.[501]

(3) The decision not to renew the marketing authorisation for Detralex

(a) The reasonableness of Poland's Measures and whether they were taken for a public purpose

Servier's Arguments

283. Servier claims that there was no reasonable relation between the protection of public health and the measures adopted by Poland with respect to Detralex.[502] Indeed, Servier claims that Poland's measures were blatantly contrary to law, served no public health interest, and were a pretext for taking Servier's products off the market.[503]

284. As an initial matter, and as discussed (*see supra* para. 47), the Parties agree that, under Article 14 of the Act on Introductory Provisions and Articles 30(1)(2)-(4) of the 2001 Pharmaceutical Law, a harmonisation application may only be denied on the basis of concerns with the product's safety, efficacy, or quality composition. [redacted]

286. Servier recounts communications from the Diosmin Advisory Team ("Diosmin team") which apparently reveal a "foregone conclusion" to deny the Detralex application and a

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[501] Respondent's Second Post-Hearing Brief, para. 24.

[502] Statement of Claim, paras. 217, 221, 224.

[503] Reply, para. 286.

[504] Reply, paras. 32-34; Claimants' First Post-Hearing Submission, para. 24; Rejoinder, para. 23.

[505] Claimants' First Post-Hearing Submission, paras. 21-30.

succession of conflicting and incoherent positions leading to the non-renewal of the marketing authorisation:[506]

(a) According to Servier, the Parties are in agreement that the February 2008 meeting was the first substantive discussion by the Diosmin team.[507] Servier submits that that team explored legal grounds for denying the application, but identified no plausible ground. No doubts were raised regarding safety, efficacy, or quality.[508]

[redacted]

[506] Reply, para. 297; Claimants' First Post-Hearing Submission, para. 31; *see also* Claimants' Second Post-Hearing Submission, para. 48.

[507] Claimants' Second Post-Hearing Submission, para. 49.

[508] Claimants' First Post-Hearing Submission, paras. 31-32.

[509] Reply, para. 294.

[510] Claimants' First Post-Hearing Submission, para. 33 (quoting Exhibit R-91, Minutes of the Diosmin Advisory Team meeting dated 28 Mar. 2008)

[511] Reply, para. 294.

[512] Reply, paras. 295-296; Claimants' First Post-Hearing Submission, paras. 34-36.

[513] Claimants' First Post-Hearing Submission, para. 37.

[514] Claimants' First Post-Hearing Submission, paras. 38, 47.

[redacted]

[515] Reply, para. 293 [redacted]

[516] Claimants' First Post-Hearing Submission, paras. 39-40.

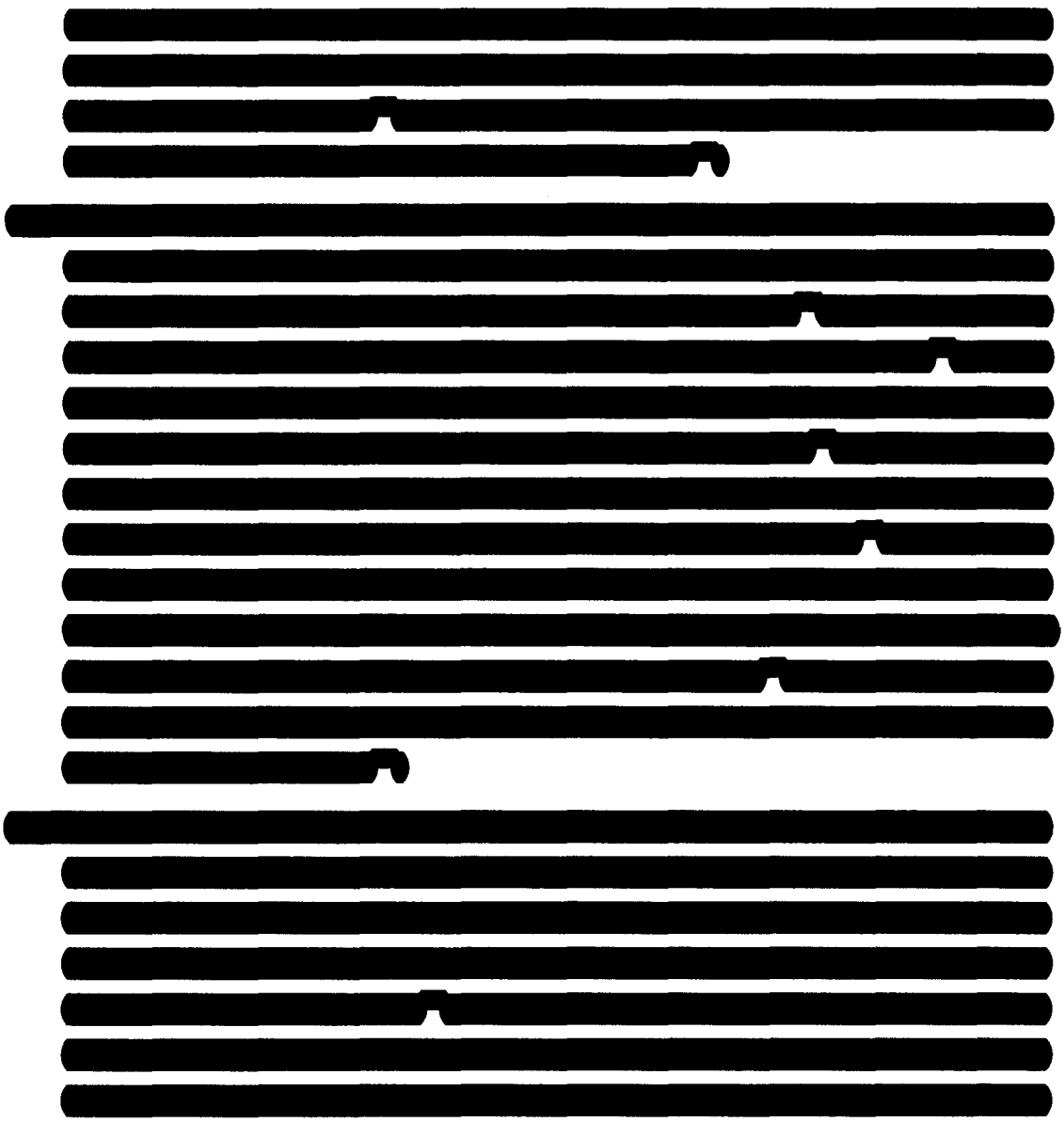
[517] Reply, para. 293 (quoting Exhibit C-50, Decision of the Minister of Health No. OR/0114/08 on refusal to harmonise Detralex dated 19 Dec. 2008).

[518] Claimants' First Post-Hearing Submission, para. 41.

[519] Claimants' First Post-Hearing Submission, paras. 41-42.

[520] Claimants' First Post-Hearing Submission, paras. 43-44.

[521] Reply, para. 292.



[522] Claimants' Second Post-Hearing Submission, para. 43; Claimants' First Post-Hearing Submission, para. 47.

[523] Claimants' First Post-Hearing Submission, para. 47; *cf.* Respondent's First Post-Hearing Submission, para. 46(v).

[524] Statement of Claim, para. 219; Reply, para. 287.

[525] Reply, para. 290.

[526] Claimants' Second Post-Hearing Submission, para. 39.

[527] Reply, para. 288; Supplement, paras. 15-20.

[528] Reply, para. 291 (quoting Act on Pharmaceutical Law, Article 25(1)). The Respondent refers to Article 25 of the Pharmaceutical Law at paras. 88 and 131 of its Statement of Defence.

[529] Reply, para. 291.

[530] Reply, para. 302; Claimants' First Post-Hearing Submission, para. 51.

[redacted]

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[531] Claimants' First Post-Hearing Submission, para. 51; Reply, paras. 305-306. In addition, Servier submits that, [redacted] Reply, paras. 306-307; Claimants' First Post-Hearing Submission, para. 48.

[532] Claimants' First Post-Hearing Submission, para. 53.

[533] Claimants' First Post-Hearing Submission, para. 51.

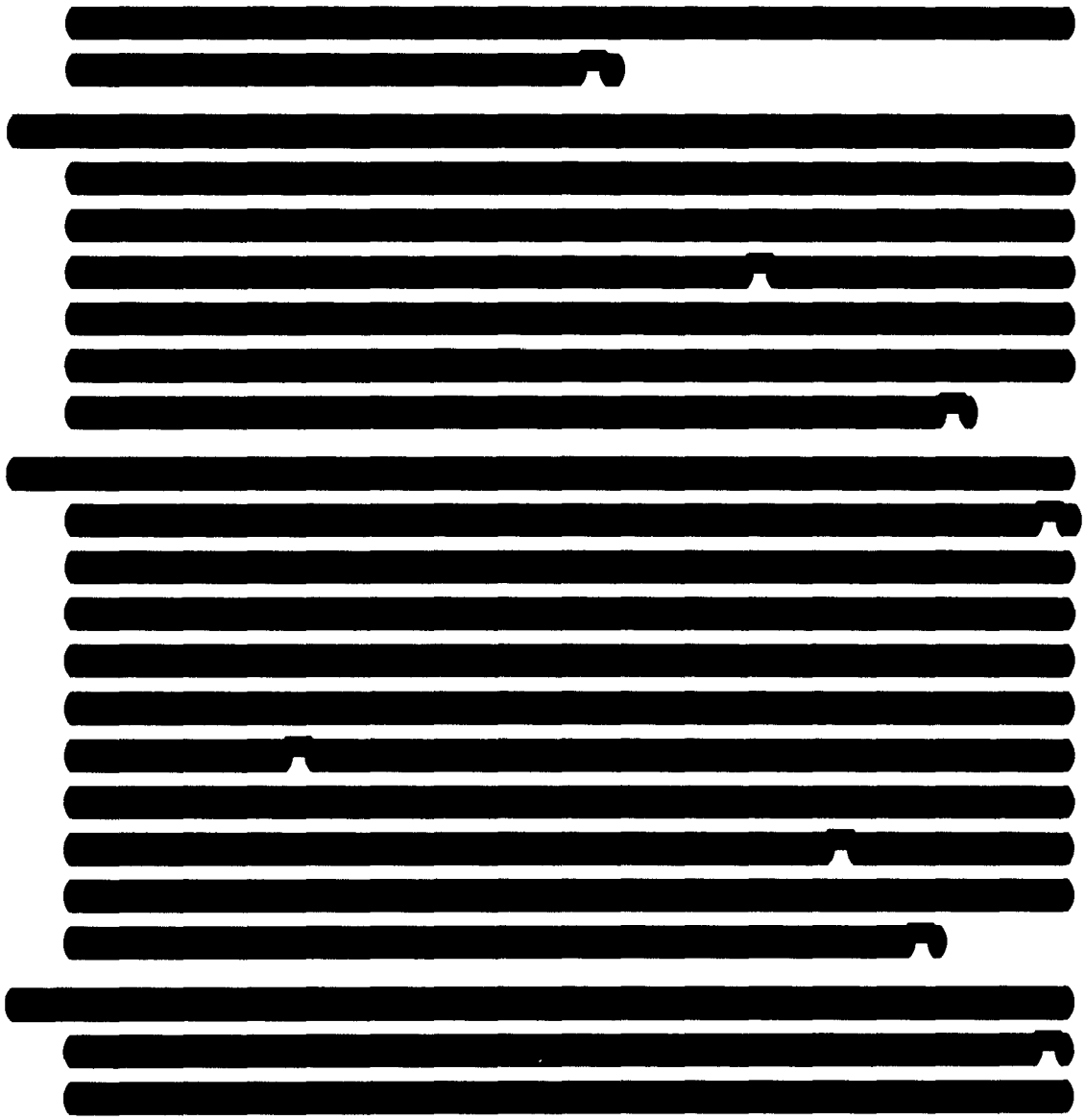
[534] Claimants' First Post-Hearing Submission, para. 54.

[535] Claimants' First Post-Hearing Submission, para. 56.

[536] Claimants' First Post-Hearing Submission, para. 55.

[537] Claimants' First Post-Hearing Submission, para. 50.

[538] Claimants' First Post-Hearing Submission, para. 49; *see also* Claimants' Second Post-Hearing Brief, para. 42.



[539] Claimants' First Post-Hearing Submission, para. 50.

[540] Claimants' First Post-Hearing Submission, para. 57.

[541] Claimants' First Post-Hearing Submission, para. 58.

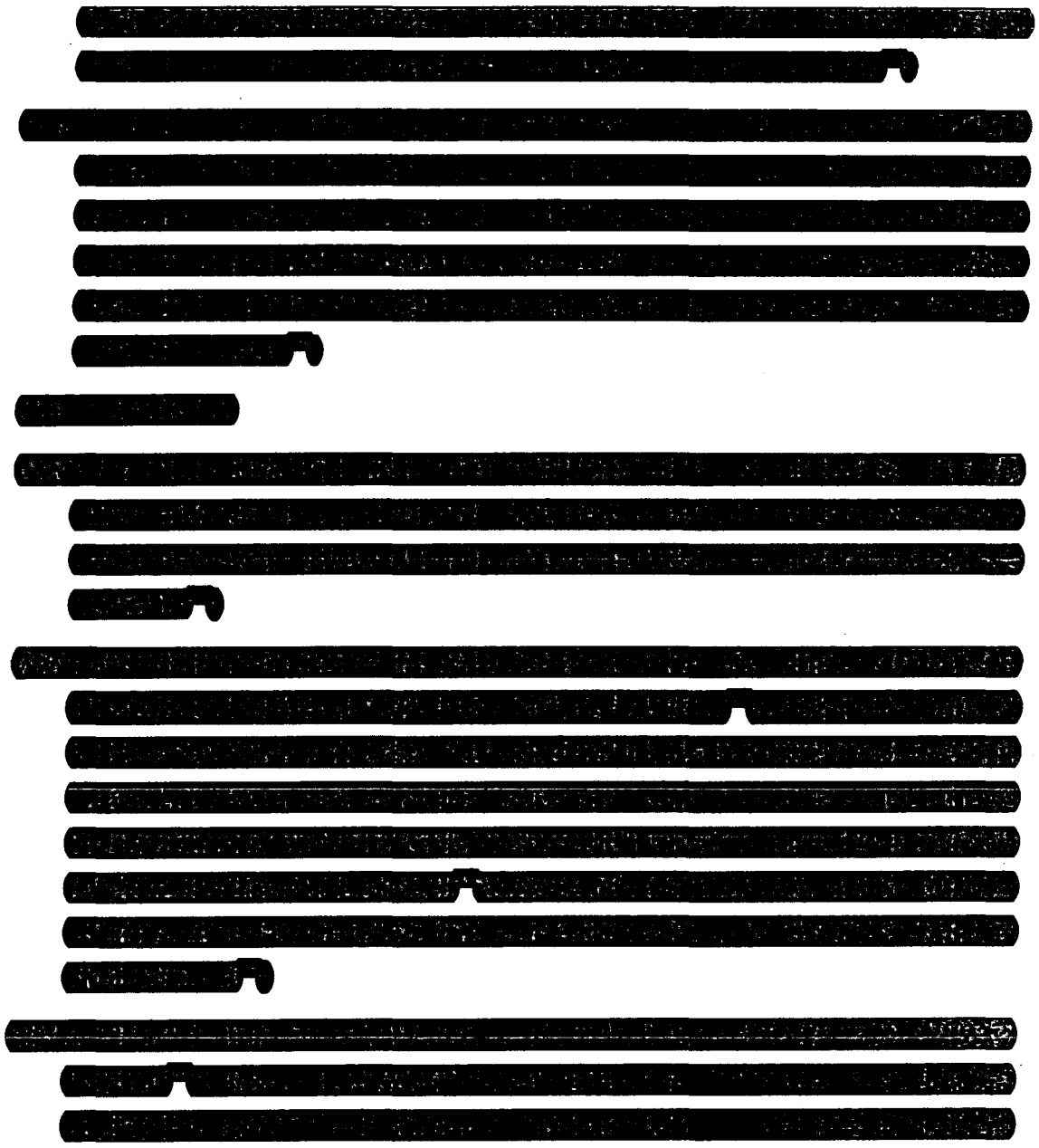
[542] Statement of Claim, para. 218 (referring to Exhibit C-50, Decision of the Minister of Health no. OR/0114/08 on refusal to harmonise Detralex and Exhibit C-52, Decision of the Minister of Health no. UD/0005/09 dated 25 Feb. 2009 – upholding decision refusing harmonisation of Detralex).

[543] Statement of Claim, para. 220.

[544] Reply, paras. 287, 302.

[545] Statement of Claim, para. 218.

[546] Reply, para. 299; Claimants' First Post-Hearing Submission, para. 48.



[547] Reply, paras. 299-301, 289. *See also* Statement of Claim, para. 220; Claimants' First Post-Hearing Submission, para. 48 (referring to Exhibit C-184, Letter from the Polish Vascular Society and Phlebology Society to the Minister of Health dated 13 Feb. 2009, pp. 1-2 and Exhibit C-185,

[548] Claimants' First Post-Hearing Submission, paras. 59-60.

[549] Statement of Defence, paras. 493-502; Respondent's First Post-Hearing Brief, para. 74.

[550] Respondent's First Post-Hearing Brief, para. 73 (citing Tr. 527:5-14 (Testimony of Mr. Cessak)).

[551] Rejoinder, para. 287 (referring to Exhibit R-166); Respondent's First Post-Hearing Brief, para. 74.

[552] Rejoinder, para. 277(v) (referring to Exhibits C-82 and R-170); Respondent's First Post-Hearing Brief, para. 76.

[553] Statement of Defence, para. 494.

[redacted]

554 Statement of Defence, para. 495; *see also* Respondent's Second Post-Hearing Brief, para. 31.

555 Rejoinder, paras. 280-281 (referring to Exhibit R-216).

556 Respondent's First Post-Hearing Brief, para. 43; Respondent's Second Post-Hearing Brief, para. 25.

557 Respondent's First Post-Hearing Brief, para. 44.

558 Statement of Defence, para. 501; Respondent's First Post-Hearing Brief, para. 52.

559 Respondent's First Post-Hearing Brief, para. 52.

560 Respondent's First Post-Hearing Brief, para. 44.

561 Respondent's First Post-Hearing Brief, para. 49.

[redacted]

[562] Respondent's First Post-Hearing Brief, para. 46.

[563] Respondent's First Post-Hearing Brief, para. 50. [redacted] Rejoinder, para. 277; Respondent's Second Post-Hearing Brief, para. 27 (citing Tr. 680:18-23) [redacted].

[564] Respondent's First Post-Hearing Brief, para. 48; Respondent's Second Post-Hearing Brief, para. 26.

[565] Respondent's Second Post-Hearing Brief, para. 32.

[566] Respondent's First Post-Hearing Brief, para. 75.

[567] Respondent's Second Post-Hearing Brief, para. 28.

[568] Respondent's Second Post-Hearing Brief, paras. 28-29.

[569] Respondent's First Post-Hearing Brief, para. 51.

[570] Rejoinder, para. 282.

[571] Rejoinder, para. 283.

[572] Rejoinder, para. 285 (referring to Exhibit R-39).

[573] Respondent's First Post-Hearing Brief, para. 96.

[redacted]

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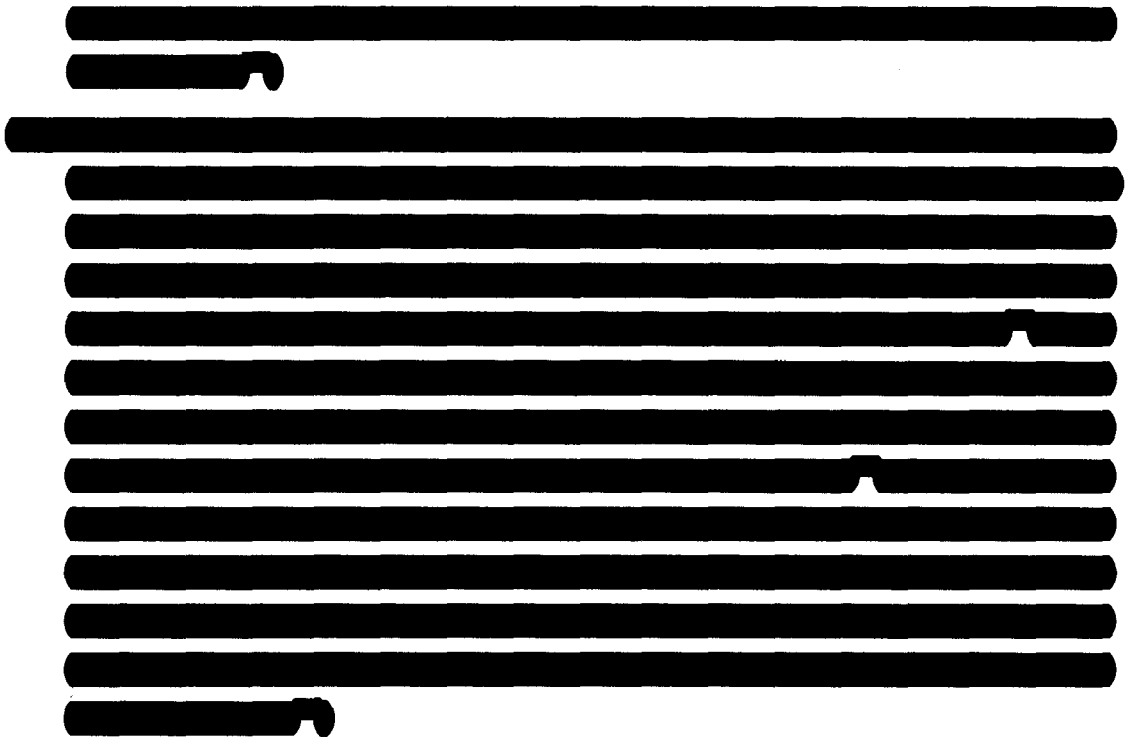
574 Respondent's First Post-Hearing Brief, para. 98.

575 Respondent's First Post-Hearing Brief, para. 98.

576 Respondent's First Post-Hearing Brief, para. 100.

577 Respondent's First Post-Hearing Brief, para. 101; Rejoinder, para. 284.

578 Respondent's First Post-Hearing Brief, para. 102.



(b) Whether Poland's actions were discriminatory

Servier's Arguments

310. Servier submits that it is well-established under international law that discrimination includes treatment that, while not being discriminatory in law, nonetheless has a *de facto* discriminatory impact on a foreign investor.[583] Servier thus claims that the measures adopted by Poland were discriminatory procedurally, substantively, and in effect, because each of those measures granted more favourable treatment to Polish-owned competitors of Detralex than they granted to Servier.[584]

311. The non-renewal of Detralex was preceded by the issuance of marketing authorisations for the medicines Diosminex and Pelethrocin, manufactured by Polish entities LEK-AM and

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[579] Respondent's First Post-Hearing Brief, para. 104; Rejoinder, para. 284.

[580] Respondent's First Post-Hearing Brief, para. 68; Rejoinder, para. 288 (referring to Exhibit C-50).

[581] Respondent's First Post-Hearing Brief, para. 68.

[582] Respondent's First Post-Hearing Brief, para. 69.

[583] Claimants' Second Post-Hearing Submission, para. 54.

[584] Statement of Claim, para. 230; Reply, para. 333; Supplement, paras. 5-7.

Blubit,[585] respectively. The Polish authorities found these drugs to be generic equivalents of Detralex. These medicines were registered as generics of Detralex despite the inability on the part of their manufacturers to demonstrate that their products contained the same active ingredient as, and were bioequivalent to, Detralex.[586]

[redacted]

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585 According to Servier, Pelethrocin was registered in Poland in June 2002 by the Greek company HELP as an alleged generic of Detralex. Pelethrocin is represented and marketed in Poland by the Polish company Blubit. Statement of Claim, para. 67.

586 Statement of Claim, para. 232; Reply, paras. 337, 339-340.

587 Statement of Claim, paras. 233-234.

588 Claimants' First Post-Hearing Brief, paras. 61-66; *see also* Claimants' Second Post-Hearing Submission, paras. 55-57.

589 Claimants' First Post-Hearing Brief, paras. 67-68.

315. Servier finds confirmation of the discriminatory nature of Poland's measures in its registration of Diosminex and Pelethrocin on the basis of well-established use. It observes that at first LEK-AM and Blubit attempted to register their products as direct generics of Detralex. However, once the Polish authorities in mid-2008 decided not to extend the marketing authorisation for Detralex (which had been listed as the reference product for the generics[590]), LEK-AM and Blubit were allowed by the Ministry to change to the well-established use procedure.[591] They were permitted to do so, Servier claims, despite the Diosmin Advisory Team acknowledging that Pelethrocin's specifications did not comply with those of Detralex or the Phar. Eur., and despite the absence of any evidence that Diosminex contained MPFF as its active substance or was bioequivalent to Detralex.[592] Moreover, on the basis of the statement of the Diosmin Advisory Team in February 2008 that the "decision [to classify Diosminex in the well-established use category] was issued already some time ago," Servier asserts that this decision was taken by the Polish authorities "somewhere in the shadow," and given to the Diosmin Team as predetermined.[593] By virtue of relying on the well-established use procedure, Polish authorities granted marketing authorisations to Diosminex and Pelethrocin while refusing to extend the marketing authorisation for Detralex on the basis of the very same data and publications generated by the clinical trials for Detralex.[594]

316. Servier disputes Poland's assertion that the registration of Diosminex did not take place in the context of the harmonisation process. According to the CJEU, these authorisations were made in that context and in order to allow local products illegally to abuse the harmonisation process.[595] Servier also asserts that the record shows that Poland processed Diosminex's initial marketing authorisation application contemporaneously with that of Detralex.[596]

317. According to Servier, the procedure that Poland followed in deciding the marketing authorisation was also discriminatory: Servier filed its application for harmonisation in early 2004, no action was taken on it for two years, and it was not decided until five years had elapsed. By contrast, (1) LEK-AM filed its application for Diosminex in late 2007, and it

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590 Reply, para. 337.

591 Statement of Claim, para. 237.

592 Reply, para. 342; Claimants' First Post-Hearing Submission, para. 69.

593 Claimants' First Post-Hearing Submission, paras. 69-72.

594 Statement of Claim, para. 237; Claimants' First Post-Hearing Submission, para. 72.

595 Reply, paras. 70-74, 335; Claimants refer to Exhibit C-130, *European Commission v. Poland*, European Court of Justice Judgment dated 22 Dec. 2010, Case C-385/08.

596 Reply, para. 336.

was approved within a year; and (2) consideration of Pelethrocin's application was similarly rapid.[597] Servier submits further that the authorities granted LEK-AM the right to supplement its registration dossier even after the renewal was granted, but no such courtesy was granted to Servier.[598]

318. Servier further claims that the Ministry also discriminated against it in comparison to other producers of innovative drugs. Servier's declaration that Detralex was already registered on the basis of the same documentation in other EU countries was not accepted by the Ministry as sufficient to extend its marketing authorisation, contrary to the cases of other innovative manufacturers in the same situation.[599]

Poland's Arguments

[redacted]

320. Poland denies that the *initial* registrations of Diosminex and Pelethrocin demonstrate the discriminatory treatment of Detralex's subsequent renewal application. Poland contends that those decisions pre-date the decision on Servier's application by four and a half years in the case of Diosminex, and six and a half years in the case of Pelethrocin. Further, they were made under different legislation—the 1991 Pharmaceutical Act—and at a point in time when the sale of Detralex was authorised in the Polish market.[601]

[redacted]

322. Poland states that there was no substantive discrimination during the harmonisation process.

[redacted]

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[597] Reply, para. 341; *see also* Supplement, paras. 8-11.

[598] Reply, para. 343.

[599] Statement of Claim, para. 238.

[600] Statement of Defence, para. 503; Respondent's First Post-Hearing Brief, para. 78.

[601] Statement of Defence, para. 504; *see also* Rejoinder, para. 291; Respondent's First Post-Hearing Brief, para. 80.

[602] Respondent's Second Post-Hearing Brief, para. 37.

[redacted]

323. Poland rejects Servier's assertion that the applications for Diosminex and Pelethrocin were processed faster than that of Detralex. Poland refers to the chronology set out in its Statement of Defence, showing the numerous steps taken in the Detralex process and the fact tha[redacted][605]

324. In response to Servier's claim that LEK-AM and Blubit were allowed by the Ministry to change to the well-established use procedure, and thus treated more favourably than Servier, Poland states that the choice of category is ultimately for the applicant. It had no involvement in LEK-AM's choice, and did not act irregularly in suggesting changes to HELP.[606]

325. In response to Servier's allegation that the decision to classify Diosminex under the well-established use category was taken "somewhere in the shadow ... without consulting the Diosmin Advisory Team", Poland reiterates that Servier has not shown that this decision was incorrect, while Servier's concerns relating to the timing and identity of the decision-maker are misconceived and therefore cannot support Servier's allegations of discrimination.[607]

326. The Diosmin Advisory Team noted that Pelethrocin could not be harmonised as a generic of Detralex, but could be harmonised under the well-established use category. Poland points out that the team made similar statements as to what was required for Detralex to have its marketing authorisation renewed.[608] Also, Poland clarified that HELP was never "required to change to the well-established use procedure, but rather was requested to use it at its discretion.[609]

[redacted]

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603 Rejoinder, paras. 300-302.

604 Rejoinder, para. 293; Respondent's First Post-Hearing Brief, para. 80.

605 Rejoinder, para. 294.

606 Rejoinder, para. 295.

607 Respondent's Second Post-Hearing Brief, para. 38 (quoting Claimants' First Post-Hearing Submission, para. 72).

608 Rejoinder, para. 297; Respondent's First Post-Hearing Brief, para. 80.

609 Rejoinder, para. 298.

[redacted]

As for Servier's allegations of discriminatory treatment compared to other producers of innovative drugs, Poland contends that Servier's allegations are unsupported; it has not provided any information as to either the producers or the nature of any discriminatory treatment.[612]

[redacted]

330. Finally, Poland denies Servier's suggestion that, even if it treated all applicants equally, its actions were discriminatory against Servier because they produced a "discriminatory impact" on Servier. Poland denies that it is subject to the further requirement that its equal treatment have equivalent economic impact.[618]

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[610] Rejoinder, para. 299; Respondent's First Post-Hearing Brief, para. 80.

[611] Rejoinder, para. 299.

[612] Statement of Defence, para. 507; Respondent's First Post-Hearing Brief, para. 80.

[613] Respondent's First Post-Hearing Brief, para. 79.

[614] Respondent's First Post-Hearing Brief, para. 79.

[615] Respondent's First Post-Hearing Brief, para. 79.

[616] Respondent's First Post-Hearing Brief, para. 79.

[617] Respondent's First Post-Hearing Brief, para. 79.

[618] Respondent's First Post-Hearing Brief, para. 78; Respondent's Second Post-Hearing Brief, para. 36.

(c) Whether Poland's actions were disproportionate

Servier's Arguments

331. Servier argues that the Ministry of Health's decision not to renew the marketing authorisation for Detralex was disproportionate to its stated goals.[619] Measures that would have been less harmful to Servier were available to Poland.[620]

332. In Servier's view, if the Ministry truly was concerned abou[redacted] it could have renewed the marketing authorisation subject to compliance with recommendations that Servier provide additional evidence on that point by specific dates. Servier submits that this is what the Ministry did earlier with respect to locally owned competitor products, Diosminex and Pelethrocin.[621] Servier submits that Poland allowed LEK-AM to supplement the dossier for Diosminex even after the harmonisation was granted, and granted Pelethrocin harmonisation despite a lack of information on its manufacturing method and composition, among other things. Blubit was also allowed to supplement its dossier following harmonisation.[622]

333. Servier contends that there was no issue of safety or efficacy with Detralex. The decision not to renew was disproportionate to the issues identified in the 19 December 2008 decision, which principally addressed[redacted] Servier submits that those concerns were laid to rest in subsequent correspondence between Servier and Poland and that there was no public health reason why the product's marketing authorisation could not have been renewed while questions concerning [redacted] could have been resolved.[623]

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619 Statement of Claim, paras. 225, 229; Reply, para. 324.

620 Statement of Claim, para. 226.

621 Statement of Claim, para. 226; Reply, para. 327.

622 Reply, para. 327 (referring to Exhibit C-214, Protocols of the National Medicines Institute on Pelethrocin dated 25 Nov. 2008, p. 3). Servier also refers to Exhibit C-146, Final Report from the Assessment of Chemical, Pharmaceutical and Biological Documentation dated 6 Nov. 2008, produced by Poland in response to Servier's document production and "submitted in the procedure of adopting the documentation to Pharmaceutical Law on the basis of the supplements submitted." *See* Reply, para. 85. According to that document, "[a]nalysis of data for authorisation indicates that further *supplements by way of post-registration amendments are required after the decision on extending the authorisation validity is issued.*" *Id.*

623 Reply, paras. 325-326.

[redacted]

Poland's Arguments

335. As a threshold point, Poland does not accept the proposition implicit in Servier's contentions, that a host State must choose regulatory measures which are the most conducive to the interest of the foreign investor. Rather, Servier must show that the Measures adopted by Poland were "obviously disproportionate".[625]

336. Poland asserts that Servier never requested that it be provided with an authorisation subject to recommendations. Absent a request from the applicant, as a matter of Polish administrative law it was not open to the Registration Office to consider such an option.[626] Further, the Pharmaceutical Law, which implements the EU Pharmaceuticals Directive, does not permit the issuance of marketing authorisations with recommendations.[627]

337. Poland contests Servier's submission that the refusal to renew was disproportionate to the issues identified [redacted] especially when those issues were resolved in June 2009. Poland says tha[redacted] is not why the application was refused, and therefore, the Registration Office's concerns were not resolved in June 2009.[628]

338. Finally, Poland alleges that Servier had more than 18 months from the time it was first informed of [redacted] April 2007) until the time the Ministry made its decision (December 2008) t[redacted]

339. In response to Servier's argument that the Detralex decision was disproportionate because the deficiencies fell within the ambit of [redacted]

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624 Claimants' First Post-Hearing Submission, para. 75.

625 Statement of Defence, paras. 509-510; Respondent's First Post-Hearing Brief, para. 106; Rejoinder, para. 304.

626 Rejoinder, para. 305; Respondent's First Post-Hearing Brief, para. 106.

627 Statement of Defence, para. 511. Further, Poland argues, such an authorisation would result in non-compliant products being authorised on the Polish market, which does not achieve public health goals, and is not evidence of a lack of proportionality. *Id.* para. 512.

628 Rejoinder, para. 306.

629 Statement of Defence, para. 513

not be relied upon as a ground for non-renewal, Poland submits that this argument does not in any way establish that the decision was obviously disproportionate.[630]

(d) Whether Poland's actions were taken in good faith

Servier's Arguments

340. Servier asserts that the Polish authorities did not act in good faith in conducting the administrative proceedings concerning the marketing authorisations for Detralex.[631]

341. The purpose of the harmonisation process contemplated by the Accession Treaty was to ensure that a medicine traded on the European common market would be authorised on the basis of documentation meeting EU standards.[632] Servier asserts that Detralex had been authorised in 18 EU Member States before the Ministry's decision, so there could have been no doubt that its supporting documentation conformed to EU standards.[633]

342. The decision of the Minister of Health refusing renewal of the marketing authorisation for Detralex was delivered to Servier on 5 January 2009, *i.e.*, after the marketing authorisation for Detralex had already expired on 31 December 2008. Servier claims that it was clear for both Servier and the authorities that in such a situation, it had no legal recourse to challenge the decision.[634]

343. Servier denies that it was its fault that the Polish authorities required five years to decide the harmonisation process for Detralex.[635] Servier submits that Poland has not explained how it processed the successful applications for Diosminex and Pelethrocin within 12 months while requiring 28 months to assess and deny that of Detralex. Servier insists that there is no excuse for the fact that Poland's decision was released after it was legally impossible to challenge the decision.[636]

344. Servier further submits that Poland failed to demonstrate that it reviewed the Detralex application prior to 2006, although that application was filed in January 2004. Servier, unlike Poland, does not view the testimony of [redacted] as supporting that the decision of June 2005 showed that Poland had started reviewing the merits of Servier's

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630 Respondent's Second Post-Hearing Brief, para. 39.

631 Statement of Claim, para. 239; Reply, para. 350.

632 Statement of Claim, para. 240.

633 Statement of Claim, para. 241.

634 Statement of Claim, para. 243.

635 Reply, para. 350.

636 Reply, paras. 351, 354.

application.[637] Servier argues, in this regard that any delays on its part in responding to demands from Poland during the application process are not comparable to the delays caused by Poland.[638] Besides, most of the delays attributed to Servier by Poland actually resulted from Poland's conduct.[639]

345. Servier denies that Poland's measures occurred because of delays in the preparation of documents and information by Servier. Servier maintains that it was not unusual for it to require time to prepare such highly technical materials, and that it did comply with all requests from the Polish authorities, including [redacted] According to Servier, the harmonisation file "clearly showed that [redacted] By comparison, Servier observes that missing documents in respect of Pelethrocin were submitted only in April 2010, more than 15 months after the harmonisation process ended.[641]

Poland's Arguments

346. Poland denies that the Ministry of Health deliberately delayed making its decision so that Servier would be left without legal recourse against an adverse decision. Poland contends that no evidence has been proffered to support the claim that the Polish authorities deliberately engaged in a campaign to deny Servier any procedural rights available as a matter of Polish or EU law.[642] Any contention to this effect is refuted by the fact that [redacted] Poland also notes that Servier did appeal the decision of the Registration Office before the Polish courts.[643] Poland further submits that Servier's argument that Poland's decisions were taken because of a "political storm that erupted in November 2007" is incompatible with the fact that the Registration Office raised the fundamental problems with Servier's application before November 2007.[644] Poland also asserts that Servier's interpretation of the minutes of the Diosmin Advisory Team is not

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637 Claimants' Second Post-Hearing Submission, para. 59.

638 Reply, para. 352.

639 Reply, para. 353.

640 Claimants' First Post-Hearing Submission, paras. 73-74.

641 Claimants' First Post-Hearing Submission, para. 73.

642 Statement of Defence, paras. 515, 517.

643 Statement of Defence, para. 517; Rejoinder, para. 309.

644 Respondent's Second Post-Hearing Brief, para. 41 (quoting Claimants' First Post-Hearing Submission, para. 30).

supported by any evidence. To the contrary, Mr. Cessak and Professor Mazurek did not suggest that the Detralex Decision was "a foregone conclusion", neither did Dr. Więckowska suggest that she was engaged in a conspiracy.[645]

347. Poland argues that there is no compelling evidence showing that Poland deliberately delayed the process.[646] The factual record rather shows that it was Servier's repeated requests for extensions of deadlines and refusal to submit supplemental information in a timely manner that delayed the process (the delays caused by Servier in the processing of the Detralex harmonisation application cumulatively account for a period of 32 months).[647] For example, following the specific request of the Registration Office, Servier took four months to provid[redacted] Although Servier has argued that it could not respond to Poland's 17 requests of 16 April 2007 within the 30-day time limit, it has not explained why it required four months to do so. Similarly, Servier has failed to explain its delay of 16 months in responding to Poland's request for [redacted] made in March 2007. This delay is all the more confounding in the face of clear documentary evidence tha[redacted]

348. Faced with these persistent delays, Poland argues that the Registration Office was entitled to make a decision on the available evidence.[650] There was no undue delay on the part of Poland.[651] By way of example, it was established at the hearing that, despite Servier's

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645 Respondent's Second Post-Hearing Brief, para. 42.

646 Respondent's Second Post-Hearing Brief, para. 44.

647 Statement of Defence, para. 516. Poland notes that approximately 3,000 decisions were made in the fourth quarter of 2008, with over 2,100 of them taken in November and December, *Id.* *See also* Respondent's Second Post-Hearing Brief, para. 44.

648 Respondent's First Post-Hearing Brief, paras. 92-93. [redacted] Respondent's First Post-Hearing Brief, para. 94.

649 Respondent's First Post-Hearing Brief, para. 92.

650 Statement of Defence, para. 516. Poland notes that approximately 3,000 decisions were made in the fourth quarter of 2008, with over 2,100 of them taken in November and December, *Id.*.

651 Rejoinder, para. 308.

earlier allegations that the Detralex Harmonisation Application was not reviewed until 2006, in fact it was reviewed in June 2005.[652]

349. In response to Servier's allegation that the justification of the Detralex Decision has changed over time, Poland submits that this finds no support in the evidence, referring to Servier's witnesses, the Polish Questions of 2007, [redacted] opinion of 1 December 2008, the Detralex Decision and the Detralex Reconsideration Decision.[653]

350. Poland also asserts that it was entitled to make its own assessment of whether a drug met EU requirements of safety, quality, and efficacy, and to determine the manner in which the harmonisation process would be carried out. Poland was not under an obligation to follow the regulatory determinations of other EU Member States;[654] indeed, unlike the MRP, registration in other EU Member States was not a relevant factor to be taken into account when considering an application to harmonise as a matter of EU and Polish law.[655]

(4) The decision not to renew the marketing authorisation for Eurespal Syrup

(a) The reasonableness of Poland's measures and whether they were taken for a public purpose

Servier's Arguments

351. Servier claims that Poland's decision with respect to Eurespal Syrup was contrary to law, unreasoned, contrary to public health interests, and irreconcilable with Poland's efforts to authorise locally owned products with the same active substance onto the market.[656]

352. While the decision not to renew the marketing authorisation for Eurespal Syrup was purported to be based on [redacted] it identified no serious public health concerns and no scientific basis for any such concerns.[657] According to Servier, such concerns are irreconcilable with [redacted]

The Ministry's purported concerns about Eurespal Syrup are incoherent, Servier claims,

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652 Respondent's First Post-Hearing Brief, para. 92.

653 Respondent's Second Post-Hearing Brief, para. 43.

654 Statement of Defence, para. 518.

655 Rejoinder, para. 310.

656 Reply, para. 308; Statement of Claim, paras. 217, 224.

657 Statement of Claim, para. 222.

658 Statement of Claim, para. 222 (citing Exhibit C-111, Witness statement of Dr. [redacted] paras. 12-13).

because the Ministry approved the marketing of Eurespal, containing the exact same active ingredient, in tablet form.[659]

353. That there was no public health basis for the decision not to renew the marketing authorisation is also demonstrated by the fact that a few months after its decision, the Ministry granted marketing authorisations for three generics of Eurespal Syrup containing the same active ingredient and targeting the same paediatric population (Elofen, Fenspogal, and Pulneo).[660]

354. Servier also claims that Poland's decision was unlawful.[661] [redacted]

355. Servier claims that these provisions require affirmative proof. That is, [redacted] a renewal application may only be rejected if Poland can point to studies affirmatively demonstrating [redacted][664]

[redacted]

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659 Statement of Claim, para. 222.

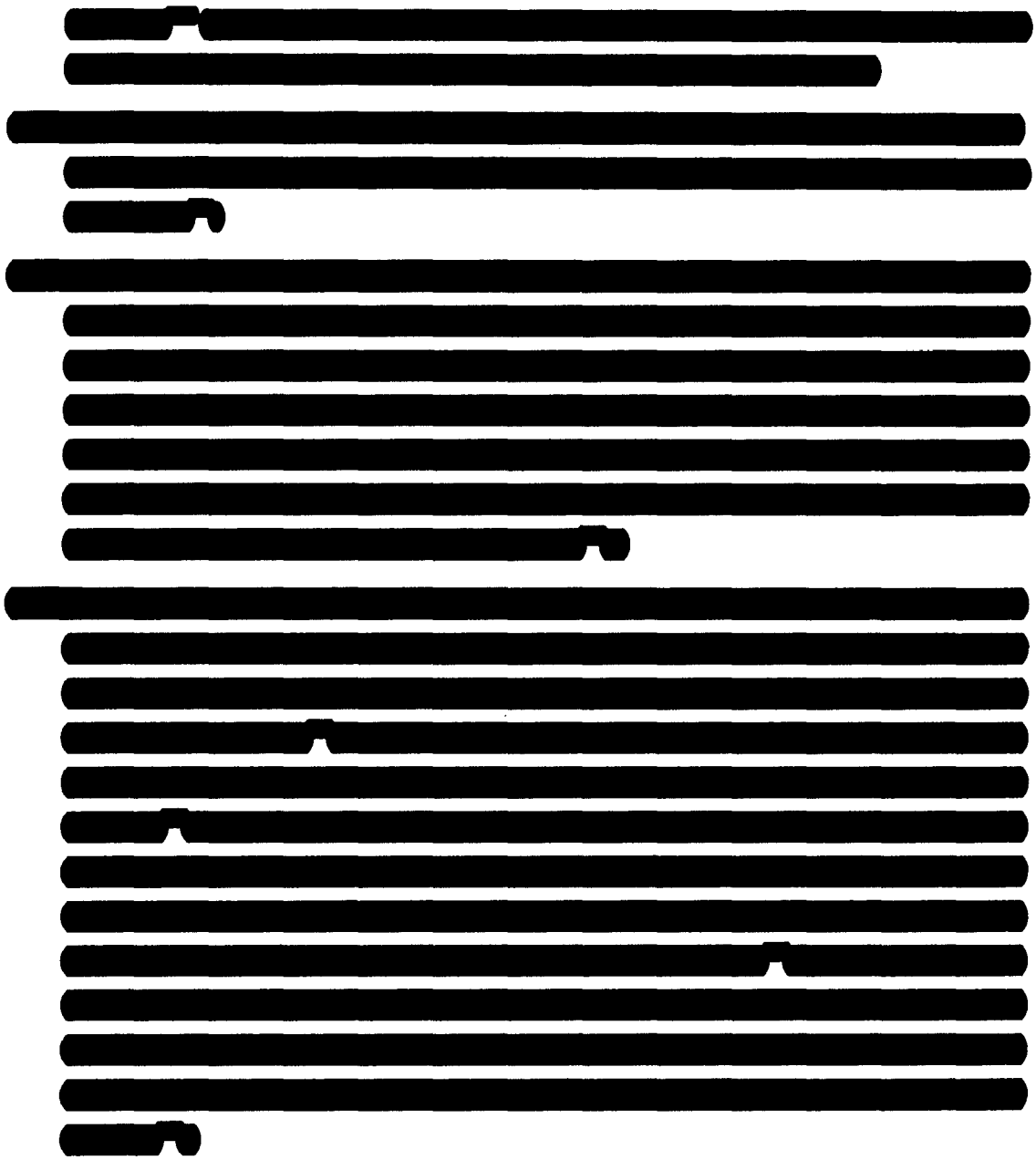
660 Statement of Claim, para. 223; Claimants' First Post-Hearing Submission, para. 80.

661 Reply, paras. 309-314.

662 Reply, para. 309.

663 Reply, para. 309 (quoting Exhibit C-187, [redacted]

664 Reply, para. 310; Claimants' Second Post-Hearing Submission, para. 34.



[665] Claimants' First Post-Hearing Submission, para. 76 (quoting Exhibit C-44, Decision of the Ministry of Health No. OR/0031/08 refusing the harmonisation of Eurespal, p. 2); *see also* Reply, paras. 311-312.

[666] Reply, para. 315; *see also* Claimants' Second Post-Hearing Submission, para. 34.

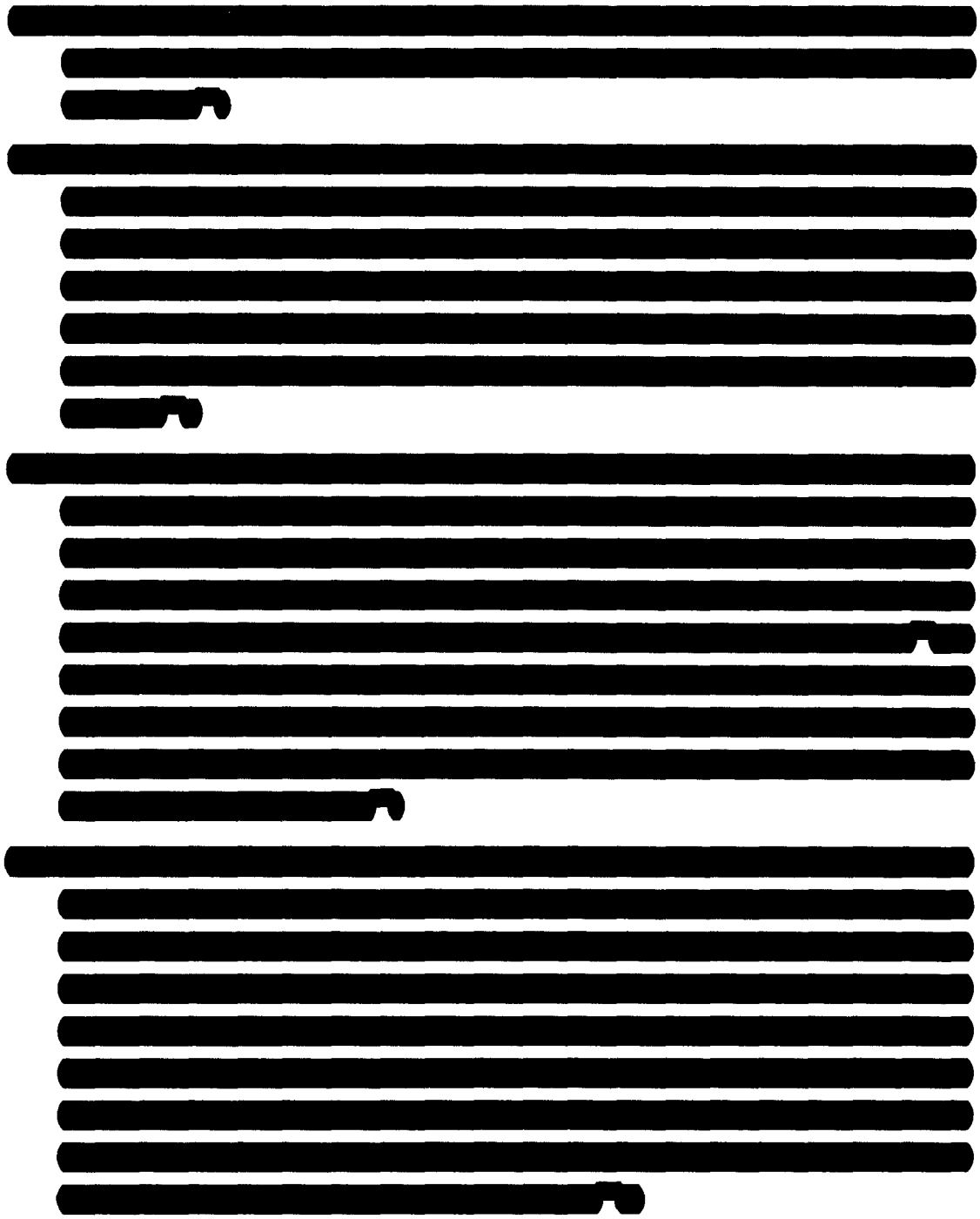
[667] Reply, paras. 316-317 (citing Exhibit C-217).

[668] Reply, para. 319.

[669] Reply, para. 319.

[670] Claimants' First Post-Hearing Submission, para. 79; Claimants' Second Post-Hearing Submission, para. 65.

[671] Claimants' Second Post-Hearing Submission, para. 64.



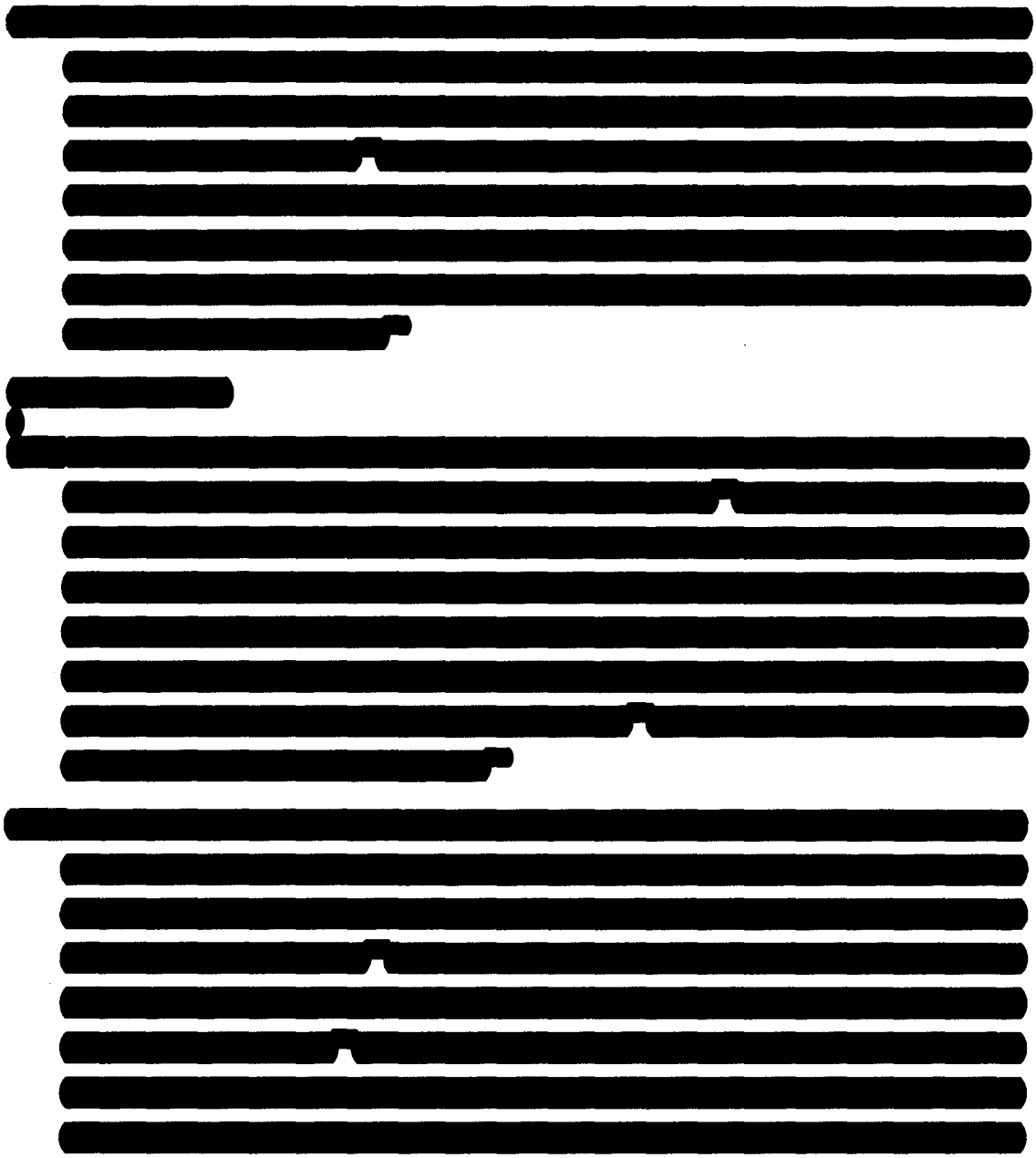
672 Reply, para. 317.

673 Reply, para. 318; Claimants' First Post-Hearing Submission, para. 77 (quoting Cessak First Witness Statement, para. 31).

674 Reply, para. 320; Claimants' First Post-Hearing Submission, paras. 81-82.

675 Reply, para. 320 (quoting Exhibit C-190, Report on the survey of all paediatric uses of medicinal products in Europe, p. 2).

676 Reply, paras. 321-322; Claimants' First Post-Hearing Submission, para. 83.



[677] Reply, para. 323 (quoting Statement of Defence, para. 259).

[678] Reply, para. 323 (quoting Exhibit R-105, Expert report on the clinical trials in children dated 30 Sept. 2008)

[679] Statement of Defence, para. 519 (referring to Pharmaceutical Law, Article 30(1)(2) and (3), and Article 10.2(4)(c) and EU Pharmaceuticals Directive, Article 26(1)(a) and (b), and Article 8(3)(i)); Respondent's First Post-Hearing Brief, para. 53.

[680] Respondent's First Post-Hearing Brief, para. 77; Respondent's Second Post-Hearing Brief, para. 64.

[681] Respondent's Second Post-Hearing Brief, para. 64.

[682] Statement of Defence, para. 519; Respondent's First Post-Hearing Brief, para. 53.

[683] Statement of Defence, para. 519; *see also* Respondent's Second Post-Hearing Brief, para. 59.

[redacted]

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684 Rejoinder, paras. 318, 320, 323.

685 Statement of Defence, para. 520 (for Poland's submissions on the specific shortfalls of Servier's application, *see* para. 521); Rejoinder, para. 314; Respondent's First Post-Hearing Brief, para. 53.

686 Respondent's First Post-Hearing Brief, para. 54. [redacted]

687 Statement of Defence, para. 522; Rejoinder, para. 315.

688 Respondent's First Post-Hearing Brief, para. 53; Respondent's Second Post-Hearing Brief, para. 46.

689 Respondent's First Post-Hearing Brief, para. 53.

690 Statement of Defence, para. 523.

691 Statement of Defence, para. 523.

[redacted]

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692 Respondent's First Post-Hearing Brief, paras. 55, 57, 64; Respondent's Second Post-Hearing Brief, para. 45.

693 Respondent's First Post-Hearing Brief, para. 56.

694 Respondent's Second Post-Hearing Brief, para. 51.

695 Rejoinder, para. 321; Respondent's First Post-Hearing Brief, paras. 55, 57.

696 Respondent's First Post-Hearing Brief, para. 58; see also Respondent's Second Post-Hearing Brief, para. 50.

697 Respondent's Second Post-Hearing Brief, para. 48.

698 Respondent's First Post-Hearing Brief, para. 59.

699 Rejoinder, para. 324.

[redacted]

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700 Rejoinder, para. 325.

701 Respondent's First Post-Hearing Brief, para. 56; Respondent's Second Post-Hearing Brief, para. 49.

702 Rejoinder, para. 326(i).

703 Rejoinder, para. 326(ii).

704 Respondent's First Post-Hearing Brief, para. 62, Rejoinder, para. 326(iii).

705 Respondent's First Post-Hearing Brief, para. 62.

[redacted]

377. With respect to the approval of marketing authorisations for the three generic syrups, Poland argues that these applications were supported by appropriate documentation (*see also infra* paras. 390 to 394).[709]

[redacted]

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706 Respondent's First Post-Hearing Brief, para. 61.

707 Statement of Defence, para. 524.

708 Rejoinder, paras. 330-331.

709 Statement of Defence, para. 524.

710 Respondent's First Post-Hearing Brief, para. 69.

711 Respondent's First Post-Hearing Brief, para. 69.

(b) Whether Poland's actions were discriminatory

Servier's Arguments

379. Servier claims that the measures adopted by Poland were discriminatory, in that each granted more favourable treatment to Polish-owned competitors of Eurespal Syrup than to Servier.[712]

380. The Polish authorities decided to register generic equivalents of Eurespal Syrup (Pulneo, Elofen, and Fenspogal) produced by Polish manufacturers based on the fact that Eurespal Syrup is also registered by Servier under a different name (Pneumorel) in another EU member state, France. The Parties agree that the declared composition, dosage, and form for Eurespal Syrup and for the three Polish drugs are identical. When Servier applied for authorisation to continue to sell Eurespal Syrup in Poland, it was denied on the basis of the alleged [redacted] This shows discrimination against Servier, because Polish authorities arrived at different conclusions with respect to one and the same product registered on the basis of the same documentation.[713]

381. Servier rejects Poland's justifications that a different legal regime applied to the locally-owned products because they purported to be generics of Pneumorel. It notes Poland's concession that the denial of the Eurespal application in light of the approval of the three Polish drugs identical to it is "strange," and denies that Poland's actions were mandated under EU law. Rather, the situation was created by the Polish authorities "by design, as it was they who instructed the Polish producers to use the French name for Eurespal Syrup."[714] Servier submits in this respect that if Poland had serious concerns about [redacted] of Eurespal Syrup, those concerns should have prevented it from actively facilitating the registration of the generics.[715]

382. Servier rejects as misleading the statement by Poland's witness, Mr. Cessak, made at the hearing, to the effect that, although Poland had discretionary power to remove Eurespal from

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[712] Statement of Claim, para. 230.

[713] Statement of Claim, paras. 235-236; Claimants' First Post-Hearing Submission, para. 78.

[714] Claimants' First Post-Hearing Submission, paras. 85-86; Claimants' Second Post-Hearing Submission, para. 61.

[715] Claimants' Second Post-Hearing Submission, para. 61.

the market, it was bound by the decision of the French regulator with respect to the Polish generics.[716] Servier's view rests on five separate reasons.

383. First, Mr. Cessak's statement is hearsay. Mr. Cessak was not responsible for evaluating applications to register generic products at the time the decisions were taken on Pulneo and Elofen, but instead relied on a letter from the French regulator not produced in this arbitration.[717]

384. Second, according to Mr. Cessak, the French regulator confirmed to Poland that the Eurespal Syrup documentation was "compliant with the acquis." In Servier's view, this confirmation should have been sufficient to harmonise Eurespal Syrup, and Poland could have brought any remaining concerns with regard to [redacted] to the EU authorities through the Community Referral Procedure.[718]

385. Third, Servier rejects Poland's argument that it could neither verify the French regulator's position nor request documentation from the French regulator; instead, under Article 15(2) of the Polish Pharmaceutical Law, Poland could request any relevant, necessary documentation.[719]

386. Fourth, Servier denies Poland's suggestion that Pneumorel remained on the French market because the French regulator possessed different documents from those in the possession of the Polish authorities. Servier submits that the full French registration dossier, produced during this arbitration, contains exactly the same clinical trials as does the Polish dossier, and that these trials were sufficient for the French regulator to conclude that the Eurespal Syrup registration complied with the *acquis*.[720]

387. Fifth, if Poland's concerns regarding [redacted] were genuine, rather than considering itself bound by the French regulator, under Article 33 of the Polish Pharmaceutical Law and Article 116 of the EU Directive, it was required to revoke the marketing authorisations for the generics. The serious public health concerns [redacted] apply without exception to all applicants and all products [redacted]

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716 Claimants' First Post-Hearing Submission, para. 87.

717 Claimants' First Post-Hearing Submission, para. 88.

718 Claimants' First Post-Hearing Submission, para. 89.

719 Claimants' First Post-Hearing Submission, para. 90 (quoting Tr. 471:17-20) (Testimony of Mr. Cessak).

720 Claimants' First Post-Hearing Submission, paras. 91-92.

[redacted] EU law is to the same effect.[721] [redacted] Consequently, Poland's decision to refuse harmonisation of Eurespal Syrup had nothing to do with the legal grounds stated in its decision.[724]

388. Servier also states that Poland's argument is impossible to credit given that it assisted the Polish generic manufacturers in selecting the procedure that it was "forced" to follow.[725]

389. Servier also claims that the Ministry of Health discriminated against it in comparison to other producers of innovative drugs. Servier's declaration that Eurespal Syrup was already registered on the basis of the same documentation in other EU countries was—contrary to the cases of other innovative manufacturers in the same situation—not accepted by the Ministry of Health as sufficient to extend its marketing authorisation.[726]

Poland's Arguments

390. Poland submits that the requirements that were imposed on Servier were applied across the board: all applicants, whether domestic or foreign, applying for approval as original medicinal products were treated equally, [redacted] Similarly, all applicants applying for approval as generics were treated the same.[727]

391. Poland rejects Servier's allegation that its decision to authorise Pulneo, Elofen, and Fenspogal Syrups while denying an authorisation for Eurespal Syrup was discriminatory. The divergent outcomes, Poland states, were due to the fact that there was a crucial difference between Servier's application and the applications for the three other syrups: Servier sought to renew its marketing authorisation as an *original* medicinal product

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[721] Claimants' First Post-Hearing Submission, paras. 93-94; Reply, paras. 346-347; Claimants' Second Post-Hearing Submission, para. 62.

[722] Claimants' Second Post-Hearing Submission, para. 62.

[723] Claimants' First Post-Hearing Submission, para. 93.

[724] Reply, para. 347.

[725] Reply, para. 349.

[726] Statement of Claim, para. 238.

[727] Statement of Defence, para. 527; Respondent's Second Post-Hearing Brief, para. 57.

whereas the three syrups applied to be registered as *generic* products. Poland insists that the difference in regulatory categories carries significant implications for the role of the Polish authorities.[728]

392. Under the Pharmaceutical Law, applicants for generic registrations are not required to provide the results of clinical (or preclinical) trials since these have been conducted by the marketing authorisation holder of the reference product. Where the reference product is a European reference product (*i.e.*, not registered in Poland), the Registration Office is required to make certain enquiries of its counterpart regulator, but no clinical assessment is conducted. By contrast, when examining an original application (under Article 10), the authority must conduct a full evaluation of the dossier, which involves an assessment of the validity of the clinical documentation. For this reason, which is derived from EU law, Poland was not presented with clinical data on the three generic syrups, and was neither required nor competent to "look behind" the French registration of Pneumorel Syrup to assess whether clinical data presented in France warranted approval of Pneumorel Syrup for use in the paediatric population. Indeed, the Registration Office was required to follow the findings on safety and efficacy made by the French authorities.[729]

393. Poland submits that the divergent outcomes are therefore a product of the fact of different legal requirements, and not of any differentiation between Polish and French applicants.[730] Moreover, Poland submits that the validity of Poland's regulatory decisions must be assessed in light of the material available to the regulator at the time of its decision and that Poland only received a copy of the French registration dossier in the course of this arbitration and thus was not in its possession when the decision was made.[731]

394. Poland claims that the EU Pharmaceuticals Directive sets forth sound reasons for such a differentiation, *i.e.*, averting the need for duplicative and costly clinical trials on live participants.[732] It also seeks to ensure cooperation and the prevention of duplicative efforts between EU regulators.[733]

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[728] Statement of Defence, para. 527; Rejoinder, para. 332; Respondent's First Post-Hearing Brief, para. 81; Respondent's Second Post-Hearing Brief, para. 54.

[729] Statement of Defence, paras. 528-529; Rejoinder, para. 332; Respondent's First Post-Hearing Brief, para. 82.

[730] Respondent's First Post-Hearing Brief, para. 83.

[731] Respondent's Second Post-Hearing Brief, para. 56.

[732] Statement of Defence, para. 530 (citing Exhibit C-82, EU Pharmaceuticals Directive, recital 10).

[733] Statement of Defence, para. 530.

395. Poland rejects Servier's argument that [redacted]

396. Second, although it may seem inconsistent to approve the generics and simultaneously refuse Eurespal Syrup, Poland maintains that the legislation and corresponding EU law compelled such a result.[735] Poland says that the nature of the EU regulatory regime permits regulatory decisions in one Member State to have effects in other Member States. [redacted]

(c) Whether Poland's actions were disproportionate

Servier's Arguments

397. Servier argues that the Ministry of Health's decision not to renew the marketing authorisation for Eurespal Syrup was disproportionate to its stated goals.[738]

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[734] Rejoinder, paras. 334-335; Respondent's First Post-Hearing Brief, paras. 84-85.

[735] Rejoinder, para. 336; Respondent's First Post-Hearing Brief, paras. 86-87.

[736] Respondent's First Post-Hearing Brief, para. 86.

[737] Respondent's Second Post-Hearing Brief, para. 56.

[738] Statement of Claim, paras. 225, 229; Reply, para. 324.

398. As noted above, it is Servier's case that Poland encouraged Polish-owned generics of Eurespal Syrup to enter the market even though it knew that their products contained the same active ingredient, fenspiride.[739] Servier rejects Poland's explanation that those applications were different because they were not original products but were generics relying on reference products. In Servier's view, this argument cannot be credited because Poland "itself advised the generic companies to take that route."[740]

399. Second, EU law recognises that [redacted] Servier claims that EU law does not require that such products be "removed from the market pending further study and assessment."[742] At the hearing, Dr. Wieckowska confirmed that the EMA does not recommend removing products from the market only because [redacted] The decision not to renew the marketing authorisation for Eurespal Syrup was therefore unreasonable.[744]

400. Third, the decision to remove Eurespal Syrup was disproportionate when one considers that the arguments advanced by Poland only concern [redacted]

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739 Reply, para. 329.

740 Reply, para. 329.

741 Reply, para. 330 (quoting Exhibit C-189 [redacted]

742 Reply, para. 330.

743 Claimants' First Post-Hearing Submission, para. 95.

744 Reply, para. 331; Claimants' First Post-Hearing Submission, para. 96.

745 Reply, para. 332.

[redacted] The decision not to renew the marketing authorisation rather than limit its indications was disproportionate.[747]

401. [redacted]

402. Finally, Servier submits that the testimony of Poland's own witness, Dr. Wieckowska, did not support its "drastic and disproportionate" measure.[749] Dr. Wieckowska stated that she did not, in fact, recommend [redacted] but only found that [redacted] At that point, Poland should have consulted the Paediatric Committee in order to determine what steps to take in respect of Eurespal Syrup. Poland did not consult the Paediatric Committee, but instead removed Eurespal Syrup from the market.[750]

Poland's Arguments

403. Poland contends that Servier has failed to show that its refusal to renew the authorisation for Eurespal Syrup was "obviously disproportionate".[751]

404. According to Poland, absent a request from the applicant, as a matter of Polish administrative law it was not open to the relevant authorities unilaterally to restrict the proposed indications of an application. Servier, for its part, never made such a request.[752] Poland submits that the Pharmaceutical Law makes it clear that issuing a marketing

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[746] Statement of Claim, para. 228.

[747] Reply, para. 332.

[748] Claimants' First Post-Hearing Submission, para.97.

[749] Claimants' First Post-Hearing Submission, para. 98.

[750] Claimants' First Post-Hearing Submission, para. 98.

[751] Statement of Defence, para. 533; Respondent's First Post-Hearing Brief, para. 106.

[752] Rejoinder, para. 339; Respondent's First Post-Hearing Brief, para. 106. Poland submits tha[redacted] Statement of Defence, para. 531 (Poland's emphasis).

authorisation "shall mean the approval of the Summary of Product Characteristics"; thus there is no scope for a "partial" or "restricted" approval, as suggested by Servier.[753]

(d) Whether Poland's actions were taken in good faith

Servier's Arguments

405. Servier asserts that the Polish authorities did not act in good faith in conducting the administrative proceedings concerning the marketing authorisations for Eurespal Syrup.[754]

406. The purpose of the harmonisation process contemplated by the Accession Treaty was to ensure that a medicine traded on the European common market had been authorised on the basis of documentation meeting EU standards.[755] Servier asserts that because Eurespal Syrup had been authorised in 5 EU Member States before the Ministry's decision, there could have been no doubt that its supporting documentation conformed to EU standards. Accordingly, Servier argues that the Polish authorities' decision, though made under the guise of harmonisation, had nothing to do with harmonising the documentation for Eurespal Syrup with that assessed elsewhere in the EU.[756]

407. The decision of the Minister of Health refusing to renew the marketing authorisation for Eurespal Syrup was delivered to Servier on 5 December 2008, *i.e.*, just 3 weeks before its marketing authorisation was to expire. The decision indicated (for the first time) that [redacted] Servier submits that it was left with virtually no legal recourse to challenge or otherwise address this decision.[757] Servier considers that had the Polish authorities acted in good faith, they would have requested the [redacted] much earlier.[758]

Poland's Arguments

408. Poland denies Servier's allegations that its actions with regard to Eurespal Syrup were pretextual.[759] Specifically, Poland denies Servier's allegations that the Ministry of Health deliberately delayed making its decision so that Servier would be left with no ability to

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[753] Statement of Defence, para. 531 (referring to Pharmaceutical Law, Article 23.2).

[754] Statement of Claim, para. 239.

[755] Statement of Claim, para. 240.

[756] Statement of Claim, para. 241.

[757] Statement of Claim, paras. 244-245.

[758] Statement of Claim, para. 246.

[759] Respondent's First Post-Hearing Brief, para. 105.

challenge or otherwise address the Polish authority's decision of 5 December 2008.[760] Poland submits that Servier has not provided any credible evidence of bad faith conduct by the Polish authorities.[761] The Ministry of Health acted in good faith throughout the Eurespal Syrup application process.[762]

409. Poland claims that it provided Servier with abundant notice and ample opportunities to safeguard its interests. Poland asserts that from as early as 9 July 2007, nearly a year and half prior to the Eurespal Syrup decision, the Registration Office wrote to Servier setting out the deficiencies [redacted] Servier submitted [redacted] Thus, Poland contends that Servier cannot argue that it was somehow taken by surprise.[763]

3. Servier's Additional Claims

(1) Fair and equitable treatment

Servier's Arguments

410. Servier's position is that Poland has breached its obligation to provide fair and equitable treatment to Servier's investments and has treated Servier's investments in an unjustified and discriminatory manner.[764]

411. Servier claims that Poland breached the fair and equitable treatment standard with respect to Detralex *inter alia* because Poland:

(a) wrongfully registered "ghost" competitors of Detralex;[765]

(b) failed to devise clear documentary requirements in the harmonisation procedure mandated by the Accession Treaty;[766]

(c) misused the lack of clear standards to remove the products of Servier, at the same time authorising generic products to take away market share and clientele of the products from Servier;[767]

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760 Statement of Defence, para. 534-535.

761 Statement of Defence, para. 536.

762 Rejoinder, para. 341.

763 Statement of Defence, para. 535.

764 Statement of Claim, para. 279;

765 Statement of Claim, para. 282; Reply, para. 377.

766 Statement of Claim, para. 283; Reply, para. 377.

(d) demanded that [redacted][768]

(e) refused to extend Detralex's marketing authorisation on grounds that admittedly had no support in the test results before the authorities;[769]

(f) denied Servier's harmonisation applications based on patently inapplicable provisions of law;[770] and

(g) disregarded Servier's documentation submitted in support of the Detralex application, including clinical studies relating to MPFF.[771]

412. Servier claims that Poland breached the fair and equitable treatment standard with respect to Eurespal Syrup, *inter alia* because Poland:

(a) revoked the marketing authorisation for Eurespal Syrup, while assisting its Polish competitors and granting them marketing authorisations to produce the same active ingredient in the same form, but under the brands of Elofen, Pulneo, and Fenspogal;[772]

(b) found sufficient grounds for granting marketing authorisations for the generics, but failed to grant marketing authorisation to Eurespal;[773] and

(c) refused to harmonise Eurespal Syrup, on the grounds of [redacted] whereas it extended the marketing authorisation for Eurespal tablets, containing the very same active substance.[774]

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[767] Statement of Claim, para. 283.

[768] Statement of Claim, para. 283; Reply, para. 377(v).

[769] Statement of Claim, para. 283.

[770] Reply, para. 377.

[771] Reply, para. 377.

[772] Statement of Claim, para. 286; Reply, para. 337(vi).

[773] Statement of Claim, para. 287.

[774] Statement of Claim, para. 288.

Poland's Arguments

413. Poland asserts that this Tribunal has no jurisdiction over Servier's Additional Claims (*see supra* paras. 210 to 214). Notwithstanding this position, Poland submits the following arguments with respect to the merits of Servier's Additional Claims.[775]

414. Article 3 is the fair and equitable clause of the Treaty. It provides:

> Each Contracting Party undertakes to ensure, in its territory and maritime areas, fair and equitable treatment of the investments of investors of the other Party, any unjustified or discriminatory measures which might impede their management, maintenance, use, enjoyment or liquidation being prohibited.

415. It is Poland's opinion that this clause of the Treaty is narrowly drafted such that "any unjustified or discriminatory measures ... being prohibited" is not a separate and independent standard but is rather an explanation of the standard set out earlier in the provision. Poland rejects Servier's claims that this clause encompasses the "concrete principles" that Servier considers as relevant to this dispute.[776]

416. According to Poland, the standard for a breach of the fair and equitable treatment is high; it does not seek to tie the hands of a State regulator nor to substitute a tribunal's view of the appropriate course of action for that of an administrative body.[777] The fair and equitable treatment standard does not provide a general right to good governance or compensation where a State falls short of such standard.[778]

417. Poland states that its non-renewal of the marketing authorisations for Detralex and Eurespal Syrup was a good faith regulatory action for the legitimate public purpose of protecting public health.[779] Poland's actions were non-discriminatory and applied in an even-handed manner: [redacted]

Poland says that its actions with regard to Detralex and Eurespal Syrup were rationally

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[775] Statement of Defence, para. 552.

[776] Statement of Defence, para. 555 (quoting Statement of Claim, para. 273).

[777] Statement of Defence, paras. 556-562.

[778] Statement of Defence, para. 563.

[779] *See generally* Rejoinder, paras. 365-366.

[780] Statement of Defence, para. 566.

[781] Statement of Defence, para. 567.

based, in order to ensure compliance with [redacted] Poland denies that Servier could have had a legitimate expectation that its marketing authorisations would continue indefinitely given that they were granted for limited periods of time and subject to renewal.[783] Finally, Poland argues that it gave Servier numerous notices of the shortcomings of its applications and multiple opportunities to rectify said shortcomings.[784]

(2) National treatment

Servier's Arguments

418. Servier submits that Poland accorded more favourable treatment to the Polish producers of Diosminex, Elofen Syrup, Pulneo Syrup, and Fenspogal Syrup than it did to Servier.[785]

419. Specifically, Servier argues that the Polish local producers of fenspiride-based syrup had no difficulty and were actively assisted by Poland in obtaining marketing authorisations based on the reference drug Pneumorel—the brand name of Eurespal Syrup in France—whereas Poland denied Eurespal Syrup a marketing authorisation. Likewise, the marketing authorisation holders for Diosminex and Pelethrocin had no difficulty obtaining marketing authorisations based on incomplete dossiers whereas Servier's application for Detralex was rejected on [redacted][786]

Poland's Arguments

420. In Poland's view, a breach of the national treatment standard requires the investor to prove: (1) the existence of a domestic investor in like circumstances; (2) that less favourable treatment was applied to the foreign investor; (3) without a rational justification.[787] Poland argues that Servier fails to establish any of the above three elements.[788] Specifically, Poland submits that Elofen, Pulneo, and Fenspogal Syrups are not comparable to the application for Eurespal Syrup—a reference drug—because they were made under the procedure for the

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[782] Statement of Defence, para. 568.

[783] Statement of Defence, para. 568.

[784] Statement of Defence, para. 570.

[785] Statement of Claim, para. 290; Reply, paras. 380-381.

[786] Reply, paras. 380-381.

[787] Statement of Defence, para. 573.

[788] *See generally* Rejoinder, paras. 367-368.

approval of generic drugs.[789] The application for the renewal of the Diosminex marketing authorisations is not comparable to the Detralex application because the applicant in the former process complied with [redacted][790]

(3) Full protection and security

Servier's Arguments

421. Servier submits that Poland has breached its obligation to provide full protection and security to Servier's investments.[791] Servier argues that in light of the Treaty's object and purpose, Poland's obligation under this standard includes economic protection and security. Poland's treatment of Servier's investment provided no such protection and security.[792]

422. Poland's treatment of Servier's investments was unfair and inequitable, which, Servier says, automatically entails a breach of full protection and security for Servier's investments. Moreover, the Polish administration repeatedly abused Polish administrative law in its treatment of Servier's investments, and, in contrast, made every effort to facilitate issuance of marketing authorisations to the benefit of Polish or third-country competitors of Detralex (Pelethrocin and Diosminex) and Eurespal (Elofen, Pulneo and Fenspogal).[793]

Poland's Arguments

423. Poland contends that Servier's allegation that a breach of the fair and equitable treatment standard automatically entails a breach of the full protection and security standard is incorrect. Such an interpretation would wrongfully render the full protection and security standard redundant.[794]

424. [redacted]

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789 Statement of Defence, para. 574.

790 Statement of Defence, para. 574.

791 Reply, para. 382.

792 Reply, para. 383.

793 Statement of Claim, paras. 292-297.

794 Statement of Defence, paras. 576-577.

795 Statement of Defence, para. 578; Rejoinder, para. 369.

C. QUANTUM

425. The Parties agree that the measure of compensation for dispossession measures, as provided in Article 5(2) of the Treaty, is the "payment of prompt and adequate compensation, the amount of which shall correspond to the actual value of the investments in question on the day before the measures are taken or made known to the public." In addition, this compensation "shall yield, up to the date of payment, interest calculated on the basis of the appropriate rate of interest in force at the time of the dispossession."[796] Moreover, the Parties agree that the relevant date for valuation is 31 December 2008, immediately before the alleged expropriation, and both employ a discounted cash flow methodology ("DCF") to estimate expected future profits from the investments.[797]

1. The Standard of Compensation

Servier's Arguments

426. Servier advances a theory of "full reparation in the event of unlawful expropriation," supported by principles of international law.[798] Servier emphasizes the Parties' agreement to arbitration under a treaty, which "requires the Tribunal to apply international law,"[799] as well as the explicit terms of Article 8(3), which provides that the Tribunal "shall rule in accordance with the provisions of this Agreement and the rules and principles of international law."[800] Servier, moreover, asserts that the international legal principle of *restitutio in integrum* "requires that reparation 'wipe out all the consequences of the illegal act and re-establish the situation which would, in all probability, have existed if that act had not been committed.'"[801] It denies the Respondent's suggestion that Article 5(2) creates a "*lex specialis* that 'displaces the general principles of damages which would otherwise apply under customary international law.'"[802] In its view, it is "absurd" to allege that a treaty

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796 Statement of Claim, para. 298; Reply, paras. 387-388, 432; Statement of Defence, para. 580; Rejoinder, para. 373; Respondent's First Post-Hearing Brief, para. 111.

797 Claimants' First Post-Hearing Submission, para. 127 (citing Tr. 821:4-8, 23-25 (Testimony of [redacted]).

798 Reply, para. 391.

799 Reply, para. 385 (quoting *MTD Equity v. Chile*, ICSID Case No. ARB/01/7, Award (May 25, 2004), para. 87).

800 Reply, para. 392.

801 Reply, para. 386 (quoting *Case concerning the Factory at Chorzów*, PCIJ, Judgment (September 13, 1927), Series A, No. 17, p. 47); *see also* Statement of Claim, para. 301.

802 Reply, para. 390.

intended to provide additional protection to investments would at the same time "provide for a standard of reparation less protective than that of customary international law."[803]

427. The Claimants also find their theory of "full reparation" supported by the "unambiguous" wording of Article 5(2), which sets the standard of reparation as the "actual value of the investment in question."[804] Thus, "[a]ctual value . . . requires the Tribunal to 'apply the method or methods of valuation which will most closely reflect the value of the expropriated investment to the investor at the relevant time.'"[805] In other words, the Tribunal must "determine the most appropriate method of compensation to re-establish the investor in a [redacted]

428. Servier maintains that its valuation figure corresponds to the actual value—the future economic benefits—of its investments in Poland.[808] Since Servier would have enjoyed additional discounted cash flows from sales of Detralex and Eurespal Syrup absent the challenged measures, and since the challenged measures did not expropriate any assets outside Poland, the value of the assets expropriated in Poland must be measured by the difference between the cash flows Servier would have received from those assets and those which it will now receive.[809] Thus, Poland's attempt to reduce the overall value of the investments to [redacted] must fail.[810] According to Servier's economic damages expert, Mr. [redacted] where, as here, a "business opportunity"—developed by Poland through the "invest[ment of] substantial sums of money" and the [redacted]—"is extinguished at the same time as the assets . . . the entire business will be the object of valuation."[811] Thus, the "*actual*, as opposed to book, value of Servier's investment in Poland"[812] must encompass [redacted]

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803 Reply, para. 390.

804 Reply, para. 393; *see also* Statement of Claim, para. 309.

805 Reply, para. 393 (quoting *Rumeli v. Kazakhstan*, ICSID Case No. ARB/05/16, Award (July 29, 2008), paras. 785-86).

806 Reply, para. 393.

807 Reply, para. 393 (quoting Exhibit C-178, First ASY Report, pp. 9-10); *see also* Reply, para. 405.

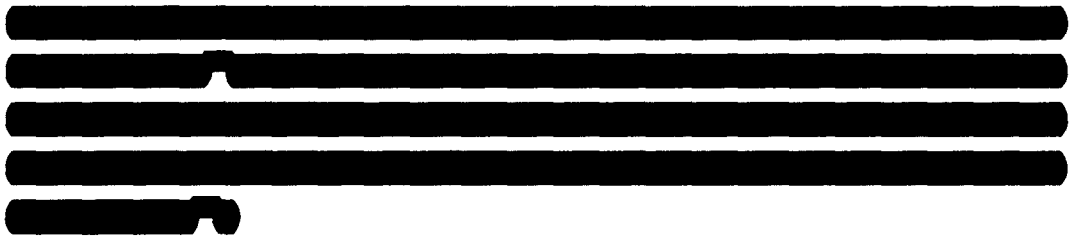
808 Reply, para. 399.

809 Claimants' Second Post-Hearing Submission, para. 79.

810 Reply, para. 400.

811 Reply, para. 401 (quoting Second Deloitte/FTI Report, paras 3.4, 3.6).

812 Reply, para. 402.



429. 

430. Drawing on international arbitration jurisprudence, Servier asserts an alternative argument: any *lex specialis* established by Article 5(2) that is inferior to "full reparation" would apply only to *lawful* measures of expropriation, and not to *unlawful* expropriation, such as the one Servier has suffered.[816] The Respondent's measures do not satisfy the criteria of public necessity, lack of discrimination, and prompt and adequate compensation, required under the Treaty for a taking to be lawful. All the more because their damages result from unlawful measures, the purpose of the valuation here is "not to determine a price that a hypothetical buyer would be willing to pay for [redacted]but to restore Servier to the financial position that it would have been in, if Poland had not adopted its unlawful measures."[817]

Poland's Arguments

431. Without prejudice to its positions that the Tribunal lacks jurisdiction and that there was no breach of the Treaty, the Respondent submits that Servier's damages submissions are flawed because they fail to value the Claimed Investments.

432. The Respondent disagrees with the Claimants as to the meaning and implications of Article 5(2) of the Treaty. According to the Respondent, the effect of Article 5(2), which limits compensation to the "actual value of the investments in question," is to create a *lex specialis* for damages under the Treaty, which displaces general principles of damages under

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[813] Reply, para. 400.

[814] Claimants' First Post-Hearing Submission, paras. 121-124, 126.

[815] Reply, para. 403 (quoting Second Deloitte/FTI Report, para. 3.16).

[816] Reply, paras. 394-395.

[817] Reply, para. 404; Claimants' First Post-Hearing Submission, paras. 131-132.

customary international law.[818] The purpose of Article 5(2) of the Treaty, therefore, is not to "wipe out all the consequences of the illegal act," as the Claimants suggest, but, rather, to "compensate the investor for the loss of the actual value of the protected investments of which it claims to have been dispossessed."[819] Poland places emphasis on the words, "investments in question." In its view, these words "put it beyond any doubt that compensation is strictly limited to the value of the investments of which an expropriation has been demonstrated. It is therefore crucial to identify with precision the relevant investments."[820]

433. The Respondent maintains that the investments protected by the Treaty ar[redacted] The Tribunal's task is to assess the value of these specific rights on 31 December 2008, if it finds that they were expropriated.[822] The Tribunal may not value or compensate the Claimants for any and all losses alleged to be causally linked to the supposed Treaty breach.[823]

434. In its damages submissions, Servier and its expert have made no attempt to identify or to value[redacted] Poland refers, first, to Servier's failure to respond to its request for documents establishing the value of the Claimed Investments for the purposes of audited financial statements or other accounting purposes. In Poland's view, therefore[redacted] Poland refers, second, to Servier's failure to instruct its expert, Mr[redacted] t[redacted] Neither of Mr.[redacted] reports defines the investments, or even acknowledges them to b[redacted]—a flaw that "goes to the very heart" of and "vitiates" the Claimants' valuation.[826] Third, Mr[redacted] adopted the DCF methodology

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818 Statement of Defence, para. 582.

819 Statement of Defence, para. 582 (quoting Statement of Claim, para. 301).

820 Rejoinder, para. 374.

821 Rejoinder, para. 374.

822 Statement of Defence, para. 583.

823 Statement of Defence, para. 584.

824 Statement of Defence, para. 586.

825 Statement of Defence, para. 587.

826 Statement of Defence, paras. 587-588; Respondent's First Post-Hearing Brief, para. 115; *see also* Rejoinder, para. 382. The Respondent points out that, at the hearing,[redacted] Moreover, the DCF valued by Mr.

to assess Servier's loss of [redacted][827]

435. Indeed, the Respondent argues that the "vast majority" of the value claimed as losses by Servier in Mr. [redacted]s reports resides in various Non-Claimed Investments not made in Poland, including [redacted][828] During his testimony at the hearing, Mr [redacted] admitted that [redacted][829] According to the Respondent's expert report ("First ASY Report"), the profits estimated by Mr. [redacted] from [redacted][830]

436. Poland underscores that Servier cannot claim that its investments are [redacted]

437. The Respondent emphasises that Article 5(2) "does not focus on the value lost by the particular investor as a result of the relevant State action," nor does it "provide a full indemnity to the investor against all alleged losses."[833] That is, it does not, as Mr [redacted] asserts, provide for damages tha[redacted]

[redacted] was generated by much more than the Claimed Investments. Respondent's First Post-Hearing Brief, para. 114.

827 Statement of Defence, para. 589; Respondent's First Post-Hearing Brief, para. 114.

828 Statement of Defence, paras. 590-591; Respondent's First Post-Hearing Brief, paras. 111, 113.

829 Respondent's First Post-Hearing Brief, para. 112 (citing Tr. 730:2-5, 747;18-23, 752;8-12, 753:4-7, 15-18, 760:6-23 (Testimony of Mr. [redacted].

830 Statement of Defence, para. 590.

831 Statement of Defence, para. 593.

832 Rejoinder, para. 374.

833 Rejoinder, para. 375.

[redacted]

438. [redacted]

439. Poland rejects the Claimants' arguments that customary international law sets a standard of compensation for expropriation—full reparation—that is higher than that under the Treaty, and that, therefore, calculating the actual value of the pleaded investments would be contrary to the object and purpose of the Treaty. The Respondent holds that there is no consensus on the standard of compensation for expropriation in international law; moreover, there is no need to look beyond the Treaty text.[840]

440. Poland further denies that a standard of full indemnity is required because any expropriation was "unlawful." It finds such a suggestion inconsistent with Servier's admission that Article 5(2) provides the standard of compensation.[841] Moreover, Servier has not demonstrated that the non-renewal decisions were not taken for reasons of public necessity and were

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834 Rejoinder, para. 380 (quoting Exhibit C-227, Second Deloitte/FTI Report, para. 3.26).

835 Rejoinder, para. 372.

836 Rejoinder, para. 387.

837 Rejoinder, para. 376 (quoting Statement of Claim, para. 209).

838 Rejoinder, paras. 377, 379 (quoting Second ASY Report, para. 12) (emphasis in the original).

839 Rejoinder, para. 378.

840 Rejoinder, paras. 389-390.

841 Rejoinder, para. 394.

discriminatory.[842] Moreover, according to Poland, the application of general international law principles would require the Claimants to establish causation, including remoteness and foreseeability. [redacted]

2. Valuation of the Claimants' Claims

Servier's Arguments

441. Relying on the theory of "full reparation", but taking a "conservative approach",[844] Mr. [redacted]ssessed: [redacted]

442. [redacted]

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[842] Rejoinder, para. 394.

[843] Rejoinder, para. 395.

[844] Reply, para. 406. [redacted] Claimants' First Post-Hearing Submission, para. 133.

[845] Statement of Claim, para. 307; Reply, para. 397.

[846] Statement of Claim, para. 308.

[redacted]

847 Statement of Claim, paras. 310-311; Reply, para. 398.

848 Statement of Claim, para. 312.

849 Claimants' Second Post-Hearing Submission, para. 78.

850 Reply, para. 410.

851 Reply, para. 411.

852 Reply, para. 412; Claimants' First Post-Hearing Submission, para. 134. [redacted] Claimants' First Post-Hearing Submission, para. 130.

853 Reply, para. 413.

[redacted]

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854 Reply, paras. 414, 416-417.

855 Reply, para. 415.

856 Claimants' First Post-Hearing Submission, para. 135.

857 Claimants' First Post-Hearing Submission, para. 135.

858 Claimants' First Post-Hearing Submission, para. 135.

859 Claimants' First Post-Hearing Submission, para. 136. [redacted] Claimants' First Post-Hearing Submission, para. 137.

860 Reply, para. 420.

861 Reply, para. 418.

862 Reply, para. 418.

[redacted]

[863] Reply, para. 419.

[864] Reply, paras. 421-422.

[865] Reply, para. 423.

[866] Reply, para. 424.

[867] Reply, para. 425.

[868] Claimants' Second Post-Hearing Submission, para. 83.

[869] Claimants' Second Post-Hearing Submission, para. 84.

[870] Reply, para. 426.

[871] Reply, para. 427.

[redacted]

Poland's Arguments

453. Contrary to the Claimants' allegation, it is the Respondent's submission that the Parties are not in agreement about fundamental methodological issues. In the ASY report the experts calculated the value of the "investments in question", while Mr. [redacted] included the value of assets beyond the "investments in question". In contrast to Mr. [redacted] ASY adopted a methodology which separated out the value of Claimed Investments and Non-Claimed Investments. According to Poland, this, and not the choice of discount rate and treatment of taxation, explains the difference in valuations of both experts.[875]

454. The Respondent submits that the actual value of the Claimed Investments is far lower than the losses claimed by Servier. According to the Respondent, [redacted]

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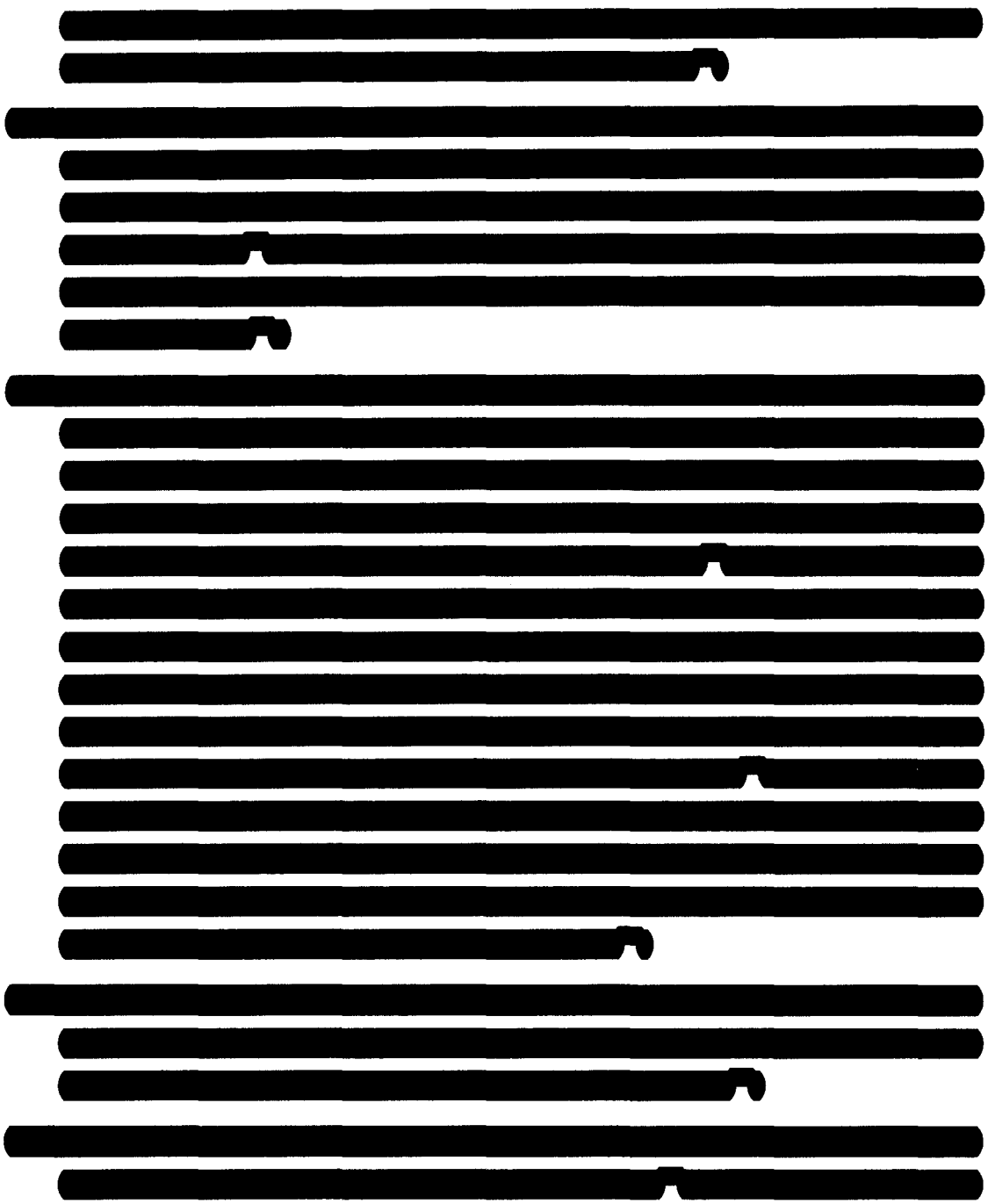
[872] Reply, para. 428; Claimants' First Post-Hearing Submission, para. 133.

[873] Claimants' First Post-Hearing Submission, paras. 127-128.

[874] Claimants' First Post-Hearing Submission, para. 128.

[875] Respondent's Second Post-Hearing Brief, paras. 69-70.

[876] Statement of Defence, para. 598.



[877] Statement of Defence, paras. 595-597.

[878] Statement of Defence, paras. 594-595; Respondent's First Post-Hearing Brief, para. 119.

[879] Statement of Defence, para. 595.

[880] Respondent's First Post-Hearing Brief, paras. 120-121.

[881] Respondent's First Post-Hearing Brief, para. 122.

[882] Respondent's First Post-Hearing Brief, para. 123.

[883] Statement of Defence, para. 598.

[redacted]

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884 Rejoinder, paras. 384, 386, 388.

885 Rejoinder, paras. 384-385.

886 Rejoinder, para. 383. [redacted] Respondent's First Post-Hearing Brief, paras. 117-118.

887 Rejoinder, para. 391.

888 Rejoinder, paras. 391-392.

889 Rejoinder, paras. 396-398 (citing Second Deloitte/FTI Report, paras. 3.32-3.35).

890 Rejoinder, paras. 398, 408.

891 Rejoinder, paras. 399, 408.

892 Rejoinder, para. 400.

[redacted]

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893 Rejoinder, paras. 401-408.

894 Respondent's First Post-Hearing Brief, paras. 117-118.

895 Rejoinder, para. 409.

896 Rejoinder, para. 410.

897 Rejoinder, para. 411.

898 Rejoinder, para. 411.

899 Rejoinder, para. 412.

900 Rejoinder, para. 425.

[redacted]

[901] Statement of Defence, paras. 616-618; Rejoinder, para. 426.

[902] Rejoinder, para. 427.

[903] Rejoinder, para. 427.

[904] Rejoinder, para. 427.

[905] Rejoinder, para. 426.

[906] Statement of Defence, paras. 619-620.

[907] Statement of Defence, para. 620.

[908] Rejoinder, para. 428 (quoting Second ASY Report, para. 55); Statement of Defence, para. 621.

[redacted]

[909] Rejoinder, para. 428.

[910] Statement of Defence, para. 621.

[911] Rejoinder, para. 429.

[912] Rejoinder, para. 430.

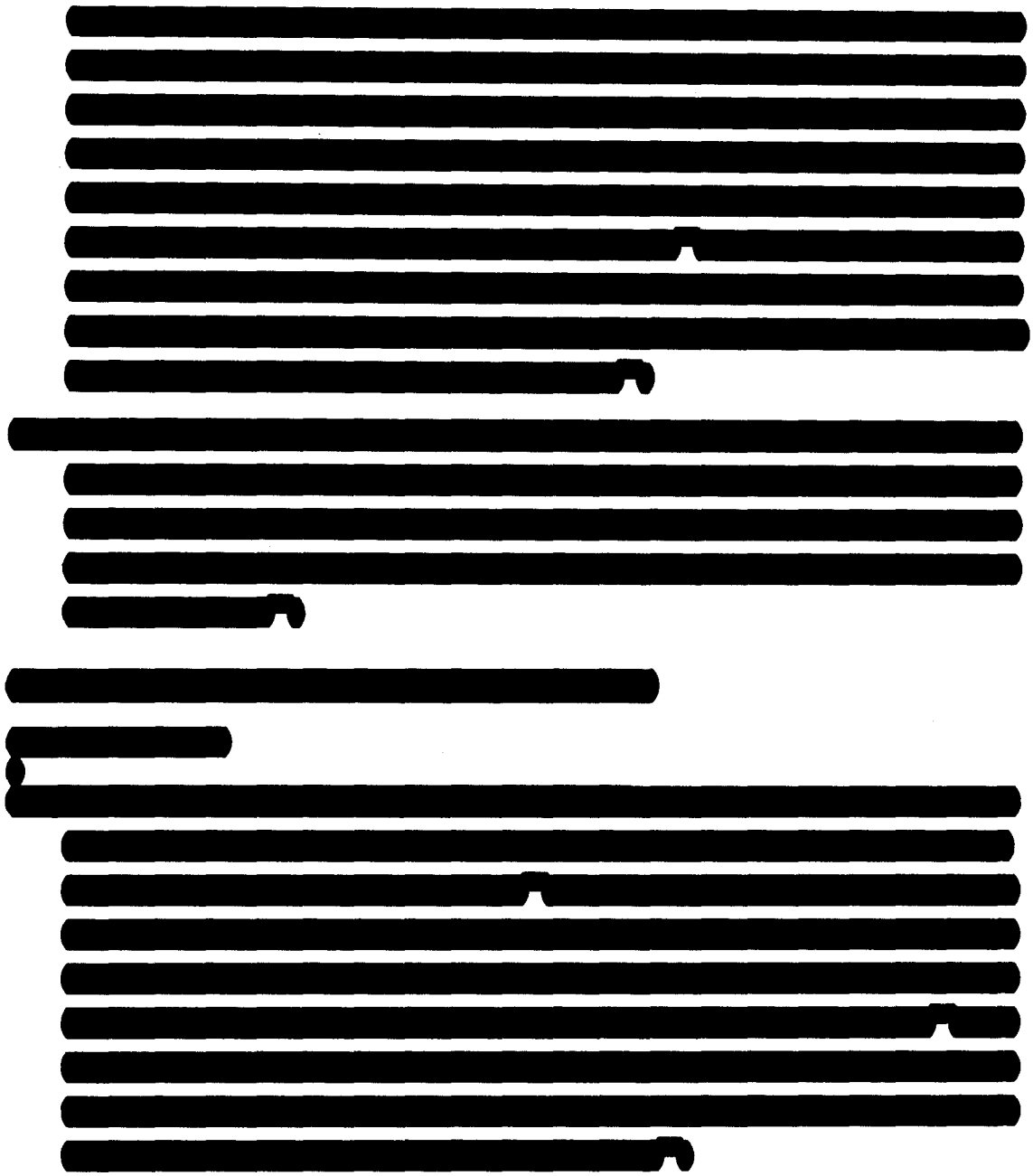
[913] Statement of Defence, paras. 622-623; Rejoinder, para. 431.

[914] Statement of Defence, para. 623; Rejoinder, para. 431.

[915] Statement of Defence, para. 624.

[916] Rejoinder, para. 432.

[917] Statement of Defence, para. 625.



[918] Statement of Defence, paras. 626-627.

[919] Rejoinder, para. 433.

[920] Respondent's First Post-Hearing Brief, para. 125.

[921] Reply, paras. 407-408.

[922] Reply, para. 408.

[923] Claimants' First Post-Hearing Submission, paras. 125-126.

471. [redacted]

472. [redacted]

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924 Statement of Defence, paras. 603, 608; Rejoinder, para. 413.

925 Statement of Defence, para. 604.

926 Statement of Defence, para. 604.

927 Statement of Defence, para. 605; Rejoinder, para. 413.

928 Statement of Defence, para. 606.

929 Statement of Defence, para. 607 (quoting Statement of Claim, Appendix 2); Rejoinder, para. 413.

930 Statement of Defence, para. 607.

931 Rejoinder, para. 413.

[redacted]

[932] Statement of Defence, paras. 610-611.

[933] Statement of Defence, para. 612; Rejoinder, para. 415.

[934] Respondent's First Post-Hearing Brief, para. 116; Respondent's Second Post-Hearing Brief, para. 71.

[935] Statement of Defence, paras. 612-614; Rejoinder, paras. 414, 417-418.

[936] Rejoinder, para. 416.

[937] Respondent's First Post-Hearing Brief, para. 116; Respondent's Second Post-Hearing Brief, para. 72.

[938] Rejoinder, para. 419; *see also* Respondent's Second Post-Hearing Brief, para. 66.

[939] Rejoinder, paras. 420-424.

[redacted]

4. Interest

Servier's Arguments

477. Servier submits that, in addition to the compensatory damages requested for its lost investment, the Treaty and the record amply support an award of interest. Servier contends that the appropriate rate is the one applicable in Poland to legal claims—a simple annual rate of 13 percent—as set forth in the Polish Civil Code by the Government's regulation of 4 December 2008, which was in force at the time of the measures at issue and remains in force today.[941] In Mr. [redacted]s preliminary calculation, simple interest at 13 percent from the effective date of the dispossession measures to the end of April 2011 amounts to [redacted] Servier denies that the Polish statutory interest rate was set at a "punitive level" or that it originates in an obscure provision of Polish law. Rather, this rate is "systematically" and "universally" applied by Polish courts to debt judgments.[943]

478. The Claimants maintain, moreover, that their request that post-award interest be compounded monthly is justified, because there is "no reason of principle precluding Poland from promptly paying compensation" should it be awarded, and because compensation "is already thirteen months overdue."[944]

Poland's Arguments

479. Poland submits that Servier's interest rates are inappropriate. Poland agrees that the award of interest and the applicable interest rate is for the Tribunal to determine in its discretion, based on the circumstances of the case.[945] However, the Respondent notes that Servier "cherry-pick[s] from Polish law"[946] a "punitive" interest rate of 13 percent, applicable under

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940 Respondent's Second Post-Hearing Brief, para. 66.

941 Statement of Claim, paras. 315-318; Reply, para. 433.

942 Statement of Claim, para. 319.

943 Reply, para. 434.

944 Reply, para. 436.

945 Statement of Defence, para. 634.

946 Statement of Defence, para. 630.

the Polish Civil Code in the context of payment of commercial invoices,[947] which results in [redacted][948]

480. By contrast, the Respondent looks to the law of the Netherlands, as the seat of arbitration, for a statutory interest rate of 3 percent per annum, compounded annually.[949] The Respondent finds this lower rate of interest particularly appropriate in light of the low global interest rate environment that prevailed during the relevant period, and in light of the fact that the calculation of the value of Servier's Claimed Investments as of 31 December 2008 means that Servier did not continue to bear the market risks associated with running a business in the competitive and regulation-intensive pharmaceuticals industry after that date.[950]

481. The Polish Civil Code, on which Servier relies, clearly states at Article 359, paragraph 2, that the interest rate is set at 13 percent "to ensure payment discipline," a purpose which does not apply in this case.[951] Here, the purpose of paying interest is compensatory; because Servier has not held the legal risk of operating this aspect of its business since 31 December 2008, the payment of interest should "reflect the lost opportunity for the claimant to generate a risk free return on its capital since the time of the expropriation."[952]

482. The rate of 3 percent proposed by Poland is also the maximum rate offered by the European Central Bank on triple 'A' rate Government bonds—a low risk investment—since the beginning of 2009.[953]

483. As to Servier's request for the post-award interest to be compounded monthly, the Respondent asserts that this "punitive" measure is rarely seen in investment treaty claims and is not justified here.[954]

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947 Statement of Defence, para. 629. The Respondent notes, in addition, that this regulation was not in force when the Eurespal Syrup Decision was taken in November 2008.

948 Statement of Defence, para. 628; Rejoinder, para. 434.

949 Statement of Defence, para. 632.

950 Statement of Defence, para. 631; Rejoinder, para. 436.

951 Rejoinder, para. 435.

952 Rejoinder, para. 435.

953 Rejoinder, para. 436.

954 Statement of Defence, para. 633.

5. Costs

Servier's Arguments

484. Servier submits that it is entitled to the entire costs of arbitration, in the amount of [redacted] It has taken a "conservative approach" to the quantification of costs, for instance by excluding the costs associated with the pre-arbitration phase, the work of Servier's employees and internal counsel, and the latter's travel related to these proceedings.[956]

485. In accordance with Article 40(1) of the UNCITRAL Rules, which provides that the costs of arbitration shall in principle be borne by the unsuccessful party, Poland should bear the costs of this arbitration, in the event Servier prevails on the merits.[957] According to Servier, these costs include the Tribunal's fees and expenses, as well as costs for the Registry, court reporters and interpreters—for which the Claimants have advanced [redacted]—as well as travel and other expenses of the Claimants' witnesses to the extent such expenses are approved by the Tribunal.[958] In fact, by establishing a procedure for witness testimony, the Tribunal has already approved the Claimants' witnesses' appearance at the hearing, and thus has now only to approve the precise amount of the expenses incurred by these witnesses.[959]

486. Moreover, in accordance with Article 40(2) of the UNCITRAL Rules, it is within the Tribunal's discretion to determine which party shall bear the costs of legal representation and assistance. Servier submits that taking into account the circumstances of this case, the Respondent should bear these costs.[960] Poland acted in an "abusive and opaque manner, applying double standards and waiting until the end of the harmonisation process to notify its decisions not to renew the marketing authorisations for Detralex and Eurespal Syrup."[961]

487. Moreover, Servier contends that the Tribunal should consider the degree of success achieved by the Parties in the arbitration, as well as the Parties' respective conduct that may have needlessly increased costs.[962] In respect to the latter, Poland's conduct has unnecessarily

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955 Claimants' First Submission on Costs, paras. 1, 3, 25; Statement of Claim, para. 320; Reply, para. 437.

956 Claimants' First Submission on Costs, para. 2.

957 Claimants' First Submission on Costs, paras. 4, 6.

958 Claimants' First Submission on Costs, paras. 7-8;

959 Claimants' First Submission on Costs, paras. 9-11;

960 Claimants' First Submission on Costs, paras. 13-14.

961 Claimants' First Submission on Costs, para. 15.

962 Claimants' First Submission on Costs, paras. 16-17.

increased the costs of these proceedings by its: (1) request for bifurcation of the proceedings; (2) reintroduction of a request for bifurcation on issues which had already been subject to the Tribunal's prior decision on bifurcation; (3) excessive document production requests which led to the production of over 86,000 pages of which the Respondent exhibited very few; (4) unfounded reliance on legal privilege in respect of statements made by Ms. Retkowska-Mika; (5) unfounded redactions of documents concerning the Diosminex and Pelethrocin files; (6) belated production of documents on 12 April 2011 that forced Servier to prepare a Supplement to its Reply Memorial; (7) petition for an Order preventing the Claimants from relying on Article 24 of the EU Pharmaceutical Directive, which was not pursued after the hearing; and (8) request to exhibit "the so-called [redacted] documents."[963]

488. Conversely, Servier finds no merit in Poland's contention that Servier increased the costs of arbitration by making "manifestly unfounded and irrelevant assertions," particularly relating to Procoralan and to the initial registrations of Pelethrocin and Diosminex.[964] Servier's position was "amply substantiated and confirmed by documentary evidence and witness statements."[965] Further, Servier argues that the Respondent's conduct concerning Procoralan is "a relevant part of the factual background" to the claims asserted in this arbitration.[966] Similarly, the illegality of the Pelethrocin and Diosminex initial registrations, and the pertaining decision of the Court of Justice of the European Union are "directly relevant to the assessment of Poland's treatment of Detralex."[967] Servier equally denies having misrepresented facts in a manner that allegedly compelled the Respondent to spend time and money on corrections.[968]

489. Regarding Poland's assertion that Servier increased the costs of arbitration by making claims beyond direct expropriation based on the MFN and Applicable Law clauses in the Treaty, Servier asserts that it is Poland that insisted on briefing the MFN clause as a preliminary matter, thus increasing the costs of the arbitration. Moreover, Servier denies having abandoned its applicable law argument at the hearing, stressing that the hearing's

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963 Claimants' First Submission on Costs, paras. 18-19.

964 Claimants' Second Submission on Costs, para. 8 (quoting Respondent's Submission on Costs, para. 7).

965 Claimants' Second Submission on Costs, para 8.

966 Claimants' Second Submission on Costs, para. 9.

967 Claimants' Second Submission on Costs, paras. 10-11.

968 Claimants' Second Submission on Costs, paras. 14-15.

purpose was to review the state of the evidentiary record and to highlight points to be addressed by witness testimony, rather than to present a comprehensive oral argument.[969]

490. Servier submits that the Respondent has provided no proof of its claim that EU avenues of redress would have been less costly than these proceedings.[970] In addition, the Respondent has failed to explain why it evaluates the additional costs allegedly caused by Servier's conduct at 30 percent of its legal costs.[971]

491. Servier's legal costs incurred include Salans legal fees and disbursements in the amount of [redacted] Deloitte fees and disbursements in the amount of [redacted] FTI fees and disbursements in the amount of $[redacted] and costs for accommodation and other expenses in relation to the hearing on the merits in the amount of [redacted][972] Servier claims that these legal costs are reasonable and proportionate and that they therefore should be compensated in full.[973] In this respect, Servier submits that the attorneys' and consultant experts' fees are based on conservative hourly rates, depending on their respective level of expertise, and that assistants with lower hourly rates were used whenever possible.[974]

492. The Claimants submit that, by contrast, the Respondent has failed to establish that its legal costs are reasonable and proportionate.[975] In fact, the fees and expenses of the Respondent's counsel exceed those of Servier's counsel by approximately 25 percent, while the Respondent's damage experts' fees and expenses are twice as high as those of Servier's experts.[976] Servier expresses surprise at the level of Poland's legal costs, given Poland's strategy in this arbitration, which consisted of attempting to cast doubt on the Claimants' case, rather than developing a positive case of its own. [977]

493. The Claimants further explain that the following factors were considered in its evaluation of overall legal costs: (1) the importance of the matter to Servier; (2) the extent and amount of damages suffered by Servier; (3) the international nature of the dispute, requiring legal representation across several jurisdictions and travel, translation and investigation

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969 Claimants' Second Submission on Costs, paras. 12-13.

970 Claimants' Second Submission on Costs, para. 16.

971 Claimants' Second Submission on Costs, para. 18.

972 Claimants' First Submission on Costs, para. 21.

973 Claimants' First Submission on Costs, para. 20.

974 Claimants' First Submission on Costs, para. 22.

975 Claimants' Second Submission on Costs, para. 1.

976 Claimants' Second Submission on Costs, paras. 4-5.

977 Claimants' Second Submission on Costs, para. 3.

arrangements; (3) Poland's conduct in this arbitration; and (4) the complexity of the factual and legal issues.[978]

494. Ultimately, Servier notes that the above-mentioned legal costs have been paid or are in the process of being paid.[979]

Poland's Arguments

495. The Respondent requests the Tribunal to order Servier to pay the entire costs of arbitration, in the amount of € 4,226,755.59 plus interest, consisting of its own costs; the costs of the arbitrators and the Registry; the legal costs and other expenses incurred by the Respondent, including the fees and expenses of its legal counsel, experts and consultants, the travel costs and other expenses of its representatives as well as the costs for translation, on a full indemnity basis; and interest thereon at such commercial rate as the Tribunal thinks fit and on a compound basis.[980]

496. The Respondent submits that Articles 38 and 40 of the UNCITRAL Rules grant the Tribunal "broad discretion and substantial flexibility" with respect to the allocation of costs, and requests that the Tribunal exercise its discretion in the Respondent's favour.[981] In particular, Poland, asserting that the Parties agree on the relevance of the "costs-follow-the-event" principle, requests that the Tribunal order the Claimants to pay all costs associated with these proceedings, should the Tribunal reject Servier's claims under the Treaty.[982]

497. In the alternative, irrespective of the outcome of the dispute, Poland submits that the Tribunal should render an award on costs in Poland's favour. In Poland's view, Servier was not willing to narrow the issues in dispute, but insisted on maintaining unfounded and irrelevant assertions, in particular in relation to the drug Procoralan, claims beyond indirect expropriation, and the registrations of Pelethrocin and Diosminex. Moreover, according to Poland, Servier made several unfounded procedural applications, including an application to introduce new evidence into the record which was subsequently withdrawn, and an application to exclude from the record evidence and information generated in the expert re-evaluation process. In addition, Servier mischaracterized certain evidence in its Reply Memorial, which forced the Respondent to spend time and costs in correcting those

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978 Claimants' First Submission on Costs, para. 23.

979 Claimants' First Submission on Costs, para. 24.

980 Respondent's Submission on Costs, para. 16 and Schedule 1; *see also* Rejoinder, para. 439.

981 Respondent's Submission on Costs, para. 5.

982 Respondent's Submission on Costs, para. 6; Respondent's Reply Submission on Costs, para. 2.

misrepresentations. Poland submits further that Servier's damages assessment is significantly inflated, while the costs of this arbitration could have been avoided if [redacted]

498. Poland alleges that Servier's conduct has directly caused the Respondent to incur additional and unnecessary costs, which account for approximately 30 percent of its overall costs of legal representation. Thus, it requests the Tribunal to order that the Claimants bear their own costs and at least 30 percent of the Respondent's legal costs, should the Claimants prevail on the merits.[984]

499. Conversely, the Respondent denies having adopted an improper conduct that warrants an adverse award on legal costs, and addresses in turn each of Servier's arguments.[985] First, Poland submits that the allegations that it "committed multiple breaches of the Treaty," "acted in an abusive and opaque manner," and "waited until the end of the harmonization process to notify its decisions not to renew the marketing authorisations for Detralex and Eurespal Syrup" were demonstrated to be "factually unfounded and legally unsustainable," and in any event pertain to the merits of the case, rather than to an assessment of arbitral costs.[986] In Poland's view, any cost inefficiencies arising from the bifurcation of the proceedings are entirely attributable to the Claimants' pursuit of its frivolous Additional Claims, its repeated changes in position, and its strenuous objection to the Respondent's request to resolve both the MFN and Applicable Law clauses' issues during the preliminary phase of the proceedings. Moreover, the Tribunal in its Decision on Bifurcation of 27 August 2010 itself acknowledged that bifurcation of the proceedings would "serve the interests of economy and efficiency."[987]

500. With respect to the Claimants' criticism of the Respondent for exhibiting only a few of the documents obtained through the document production process, the Respondent submits that this ground is not relevant to an apportionment of arbitral costs, that the Claimants submitted a substantial portion of these documents voluntarily, and that the documents that

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983 Respondent's Submission on Costs, para. 7.

984 Respondent's Submission on Costs, para. 8.

985 Respondent's Reply Submission on Costs, para. 4.

986 Respondent's Reply Submission on Costs, para. 5 (quoting Claimants' First Submission on Costs, para.15).

987 Respondent's Reply Submission on Costs, paras. 6-9.

were not produced nonetheless helped complete the Respondent's understanding and analysis of the case.[988] Furthermore, Poland asserts that its position on legal privilege with respect to statements made by Ms. Retkowska-Mika, while ultimately not favoured by the Tribunal, was based on a genuine and reasonable belief.[989] Poland's additional production of documents on 12 April 2011 was caused by a genuine dispute between the Parties with respect to the scope of the exceptions to production set out in paragraph 1(a) of the Procedural Order of 22 February 2011.[990] Poland also points out that, contrary to Servier's contention, Poland's objection to Servier's reliance on Article 24 of the EU Pharmaceutical Directive was indeed pursued in the Respondent's First Post-Hearing Brief.[991] Finally, the Respondent claims that the issue of the inclusion in the record of documents exhibited in Mr. [redacted]s expert report was a product of the Claimants' "recalcitrant approach in refusing" the Respondent's request for inclusion.[992]

501. The Respondent's legal costs comprise the fees and expenses of its experts in the amount of € 1,132,031.94; the travel costs and other expenses of its witnesses in the amount of € 8,311.12; and the costs for legal representation and assistance in the amount of € 2,746,412.53, including the fees and expenses of its legal counsel, the travel costs and other expenses of its representatives, and translation costs.[993]

502. Ultimately, the Respondent notes that it has advanced € 340,000.00 to the Registry for the fees and expenses of the arbitrators and the Registry.[994]

6. Alternative Redress and Specific Relief

Servier's Arguments

503. Finally, Servier submits that the Tribunal may properly order restitution under the Treaty, because specific performance is an accepted remedy in investment law and general public international law; because the Tribunal's power to order restitution is not limited by the omission of any reference to such a remedy in the Treaty; and because, in public

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[988] Respondent's Reply Submission on Costs, paras. 10-11.

[989] Respondent's Reply Submission on Costs, para. 12.

[990] Respondent's Reply Submission on Costs, paras. 13-14.

[991] Respondent's Reply Submission on Costs, para. 15.

[992] Respondent's Reply Submission on Costs, para. 16.

[993] Respondent's Submission on Costs, paras. 9-14, 16.

[994] Respondent's Submission on Costs, para. 15.

international law, restitution is the "first remedy," before compensation—including in situations of unlawful expropriation.[995]

Poland's Arguments

504. Poland submits that any award of damages should exclude the possibility of alternative redress, including in the form of the EU law procedures to regain marketing authorisations in Poland, in order to avoid the risk of double-recovery by Servier.[996]

505. Additionally, the Respondent denies that, in the circumstances of this case, specific relief may be granted in the form of an award immediately reinstating marketing authorisations for Detralex and Eurespal Syrup in Poland. In this regard, Poland contends that specific performance is rarely awarded in investment treaty arbitration, and is explicitly excluded here by Article 5(2) of the Treaty, which limits the remedy for expropriation to compensation in the amount of the "actual value" of the expropriated investment.[997]

506. Moreover, the Tribunal "should not attempt to substitute its assessment of the scientific arguments"[998] for the "science-based decisions of highly specialised regulatory agencies."[999] Poland's decisions involved "complex analys[e]s of many highly technical and scientific documents by the competent authorities. . .within the regulatory guidelines prescribed by. . . EU Directives and Regulations."[1000] [redacted]

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995 Reply, paras. 438-440.

996 Statement of Defence, para. 635.

997 Statement of Defence, para. 637; Rejoinder, para. 437. The Respondent additionally asserts that ordering specific performance "would be contrary to the well-established right of the State to expropriate assets." Statement of Defence, para. 637.

998 Statement of Defence, para. 639.

999 Statement of Defence, para. 638; Rejoinder, para. 437.

1000 Statement of Defence, para. 638.

1001 Statement of Defence, para. 638.

VI. RELIEF REQUESTED

507. At paragraph 441 of its Reply Memorial, paragraph 138 of its First Post-Hearing Submission and paragraph 16 of its First Submission on Costs, Servier requests that the Tribunal enter an award in its favour and against Poland as follows:

(a) dismissing Poland's objections to jurisdiction in their entirety;

(b) declaring that the Tribunal has jurisdiction in respect of this dispute and that the Claimants' claims are admissible;

(c) declaring that Poland breached its obligations under Article 5(2) of the Treaty by dispossessing Servier of their investments in Detralex and Eurespal Syrup in Poland;

(d) declaring that Poland breached its obligations to provide fair and equitable treatment, full protection and security, to avoid taking arbitrary and discriminatory measures and to provide national treatment;

(e) declaring that the value of Servier's investments in Detralex and Eurespal Syrup as of the effective date of the dispossession measures wa[redacted]

(f) ordering Poland either (i) to provide full restitution to Servier by immediately reinstating marketing authorisations for Detralex and Eurespal Syrup in Poland and compensating Servier for its losses suffered prior to the reinstatement of such authorisations or (ii) to pay compensation to Servier in the full amount of the actual value of Servier's investments in Detralex and Eurespal Syrup;

(g) declaring inadmissible and excluding from the record of this arbitration documents and information generated in the re-evaluation process, in particular (i) Exhibits R-130 through R-144 inclusive, (ii) the entirety of the witness statement of [redacted] (iii) Section 7 (paras. 71-91) of the witness statement of Prof. Mazurek pertaining to the discussion of the expert re-evaluation process, in which he participated as a Polish-appointed expert; and (iv) those portions of Poland's Statement of Defence which expressly rely on documents mentioned in items (i) through (iii);

(h) ordering Poland to pay pre-award interest at the simple annual rate of 13 percent;

(i) ordering Poland to pay the entire costs of this arbitration, including all expenses that Servier has incurred or shall incur herein in respect of the fees and/or

expenses of the arbitrators, the Registry, Servier's legal counsel, experts, consultants, and witnesses, totalling [redacted]

(j) ordering Poland to pay post-award interest at a rate of 13 per annum compounded monthly on the amounts awarded until full payment thereof; and

(k) ordering such other relief as the Tribunal shall deem just and proper.

508. At paragraph 439 of its Rejoinder, Poland requests the Tribunal to issue a Final Award:

(a) declaring that the Tribunal lacks jurisdiction in respect of this dispute or that the claims are inadmissible; or alternatively:

(b) declaring Poland has not violated any of its obligations under the Treaty, or to the extent applicable, under international law or any other legal system; and,

(c) ordering the Claimants to pay all costs incurred in connection with these arbitration proceedings including their own costs, the costs of the arbitrators and the Registry, as well as the legal and other expenses incurred by Poland including the fees of its legal counsel, experts and consultants, as well as Poland's own officials and employees on a full indemnity basis, plus interest thereon at such commercial rate as the Tribunal thinks fit and on a compound basis;

(d) such other relief as the Tribunal, in its discretion, considers appropriate.

509. At pages 20-21 of its Second Post-Hearing Brief and para. 16 of its Submission on Costs, Poland requests that the Tribunal issue an Award:

(a) declaring that the Tribunal lacks jurisdiction over Servier's claims as (1) there is no legal nexus between the impugned decisions and the Claimed Investments; (2) Servier seeks damages for injury suffered by it in its capacity as exporter;

(b) declaring that [redacted]

(c) declaring that the Tribunal lacks jurisdiction to resolve claims that Poland has expropriated any [redacted] listed in Appendix 2 to Servier's Statement of Claim, as [redacted] and

(d) declaring that the Tribunal lacks jurisdiction to resolve Servier's Additional Claims;

(e) to the extent that the Tribunal reaches the merits, declaring that Poland's measures do not contravene its obligations under Article 5(2) of the Treaty for the

following reasons, whether taken individually or jointly: (1) there has been no interference with Servier's rights in, or control over, the Claimed Investments; (2) the evidence does not establish that Poland's measures have eliminated the value of the Claimed Investments; (3) the evidence does not establish that Poland's measures can give rise to permanent or irreversible effects on the Claimed Investments; (4) Poland's measures involved a valid exercise of regulatory powers; (5) Poland's measures did not violate any legitimate expectations arising from Servier's acquisition of the Claimed Investments and Poland did not obtain any economic benefits from its measures; (6) Poland's measures were taken pursuant to obligations under the EU Treaty which is a subsequent treaty binding Poland and France; and

(f) declaring that Poland's measures do not contravene Articles 3, 4(1) and 5(1) of the Treaty;

(g) in the event the Tribunal finds Poland liable, ruling that (1) the value of the Claimed Investments, as of 31 December 2008, was [redacted] (2) the appropriate rate of interest to be applied is 3 percent per annum compounded annually; and (3) any award of damages should be reduced to account for Servier's failure to mitigate;

(h) ordering the Claimants to pay all costs incurred in connection with these arbitration proceedings including their own costs, the costs of the arbitrators and the Registry, as well as the legal and other expenses incurred by Poland including the fees of its legal counsel, experts and consultants, the travel costs and other expenses of its representatives and the costs for translation, on a full indemnity basis, plus interest thereon at such commercial rate as the Tribunal thinks fit and on a compound basis;

(i) excluding from the record of this arbitration Exhibit C-255 and the document referenced in footnote 10 of Servier's First Post-Hearing Brief; and

(j) rejecting Servier's request that all documents and information generated in the expert re-evaluation process be excluded from the record of this arbitration.

VII. THE TRIBUNAL'S ANALYSIS

A. OVERVIEW

1. Summary of Conclusions

510. For the reasons set forth below, the Tribunal concludes that it possesses jurisdiction under the France-Poland BIT with respect to assets o[redacted]

511. The Tribunal confirms the view expressed in its Interim Award of 3 December 2010 to the effect that the MFN provisions in Article 4(1) of the France-Poland BIT do not expand arbitral competence in the present proceedings, with the consequence that BIT Article 8(2) applies to restrict the Tribunal's jurisdiction to disputes relating to alleged divestment under Article 5(2), to the exclusion of the Claimants' Non-Expropriation Claims. Moreover, the Tribunal has not been persuaded that the applicable law provisions of the BIT, including Article 8(3), operate to expand its jurisdiction in these proceedings.

[redacted]

514. Prior to presenting its analysis, the Tribunal sets forth the key Treaty provisions on which it relies.

2. Key Treaty Provisions

515. BIT Article 1(1) defines "investment" as follows:

> The term "investment" shall mean assets such as property, rights and interests of any kind related to an economic activity in any sector whatsoever, in accordance with the laws of the Contracting Party in whose territory or maritime areas the investment has been made, including inter alia, but not limited to:
>
> (a) Movable and immovable property and all other real rights such as mortgages, liens, usufructs, sureties and similar rights;
>
> (b) Shares, share premiums and other forms of holdings, even minority or indirect, in companies incorporated in the territory of either Party;
>
> (c) Bonds, debts and rights to any benefit having an economic value;
>
> (d) Copyrights, industrial property rights (such as patents for inventions, licenses, registered trademarks, industrial models and designs), technical processes, registered names and clientele, provided that the said assets related to an economic activity must be or must have been invested in accordance with the laws of the Contracting Party in whose territory or maritime areas the investment is made, before or after the entry into force of this Agreement.

516. BIT Article 5(2) imposes the following host-state responsibilities with respect to divestment of an investor's property:

> The Contracting Parties shall not take any expropriation or nationalization measures or any other measures which would have the effect of divesting investors of the other Party, either directly or indirectly, of investments belonging to them in its territory or maritime areas, except for reasons of public necessity and on condition that these measures are not discriminatory or contrary to a specific undertaking.
>
> Any divestment measures that may be taken shall give rise to the payment of prompt and adequate compensation, the amount of which shall correspond to the real value of the investments in question on the day before the measures are taken or made known to the public.
>
> Such compensation, its amount and its method of payment shall be determined no later than the date of divestment. The compensation shall be effectively realizable, paid without delay and freely transferable. It shall yield, up to the date of payment, interest calculated on the basis of the appropriate rate of interest in force at the time of divestment.

517. The dispute resolution clause in BIT Article 8 provides as follows:

> 1. Any dispute relating to investments between one Contracting Party and an investor of the other Contracting Party shall, as far as possible, be settled amicably between the two parties concerned or, failing that, through internal means of recourse.
>
> 2. However, disputes relating to the divestment measures referred to in article 5, paragraph 2, particularly those relating to possible compensation, its amount and terms of payment and the interest payable in the event of a delay in payment, shall be settled according to the following conditions:
>
> If any such dispute has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute, it shall, at the request of either party, be submitted to arbitration. It shall be settled definitively in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law, as adopted by the General Assembly of the United Nations in resolution 31/98 of 15 December 1976.
>
> When both Contracting Parties have become parties to the Convention on the settlement of investment disputes between States and nationals of other States, signed at Washington on 18 March 1965, any such dispute which has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute shall be submitted for arbitration to the International Centre for Settlement of Investment Disputes.
>
> 3. The arbitral tribunal shall rule in accordance with the provisions of this Agreement and the rules and principles of international law.

B. JURISDICTION

1. Jurisdiction Ratione Personae

518. The Treaty defines an "investor" to include "[a]ny corporate body incorporated in the territory of either Contracting Party in accordance with the laws of that Party and having its registered office therein." It is common ground between the two sides that all the Claimants are incorporated and registered in France, and thus qualify as investors pursuant to the definition of BIT Article 1(2)(b).

2. Jurisdiction Ratione Materiae

(1) Non-Divestment Claims

519. The Tribunal's Interim Award of 3 December 2010 rejected the view that the Most Favoured Nation clause in the France-Poland BIT allowed invocation of provisions in other investment treaties covering so-called "Non-Expropriation Claims" related to fair and equitable treatment, non-arbitrary and non-discriminatory treatment, national treatment, and/or full protection and security of investments. The Tribunal held that the notion of "treatment" in Article 4(1) of the France-Poland BIT does not encompass international arbitration, which remained subject to the limitations of Article 8. Article 8 provides for arbitration only for divestment measures referred to in Article 5(2) of the BIT.

520. The Interim Award, however, deferred ruling on the Claimants' contention that the Tribunal might apply substantive norms related to fair and equitable treatment (BIT Article 3) and full protection and security (BIT Article 5). Such claims arguably could be entered into consideration by virtue of the BIT Article 8(3), which directs the Tribunal to "rule in accordance with the provisions of this Agreement and the rules and principles of international law." According to the Claimants, the Tribunal possesses subject matter jurisdiction to apply rules of decision that vindicate claims for fair and equitable treatment or full protection and security. In this connection, the Claimants seek support in Article 33(1) of the UNCITRAL Rules, which provides that "[t]he arbitral tribunal shall apply the law designated by the parties as applicable to the substance of the dispute."

521. The Claimants' argument on this point must fail. Although claims for expropriation and related compensation often intersect with applications related to unfair and inequitable treatment, or denial of full protection and security, each claim category remains distinct in nature, with potentially divergent evidentiary requirements, remedies and standards for quantum of compensation.

522. Jurisdiction to vindicate rights related to expropriation cannot create authority to decide claims derived from other rights in a treaty which by its terms grants recourse to arbitration only for limited types of claims, and moreover expressly provides for "internal means of recourse" as the default mechanism to address controversies connected to other substantive entitlements.

523. The drafters of the France-Poland BIT were careful to set forth the general rule that "internal means of recourse" would address disputes not resolved through amicable settlement, adding in the next sentence a "however" to introduce coverage for controverted divestment measures related to compensation and terms of payment.

524. Admittedly, as discussed below, notions of unfairness and discrimination may insert themselves into a discussion of what constitutes divestment of property.

525. However, it would constitute an unacceptable stretch of logic to presume that authority to adjudicate requests related to one set of alleged wrongs can *ipso facto* create arbitral power to decide a different variety of claims.

526. The Tribunal finds support in this conclusion in the principles set forth in Article 31 of the Vienna Convention, which stresses the "ordinary meaning" of treaty terms viewed "in their context and in the light of . . . [the Treaty's] object and purpose." Thus reference to "provisions of this Agreement" and the "rules and principles of international law" in BIT Article 8(3) must be read in light of the contextual limitation on jurisdiction contained in BIT Article 5(2).

527. The choice of forum provisions in BIT Articles 8(1) and 8(2) must be given some effect. Had the general default reference to resolution of disputes by "internal means of recourse" been inserted in *pari passu* with the arbitration provisions, one might argue that they took equal status in the Treaty's adjudicatory hierarchy, giving investors an option between one path or the other, depending on strategic or tactical considerations.

528. Such is not the structure of the France-Poland BIT, however. The arbitration provisions of Article 8(2) contain the mandatory "shall" instead of the precatory "may" followed by two paragraphs outlining reference to the UNCITRAL and ICSID arbitration schemes.

529. In the context of the current dispute, the Tribunal finds no justification for allowing choice-of-law rules to serve as a back door through which to import forum selection provisions contrary to treaty terms.

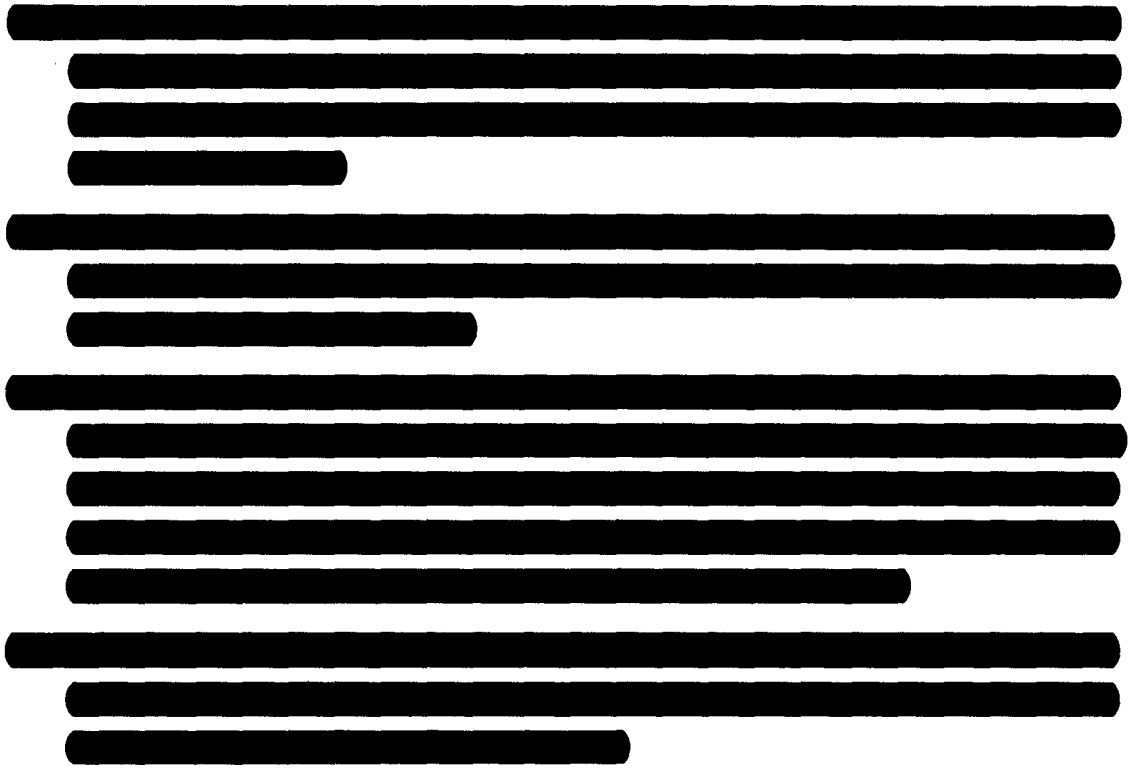
(2) Treaty-Protected Investments

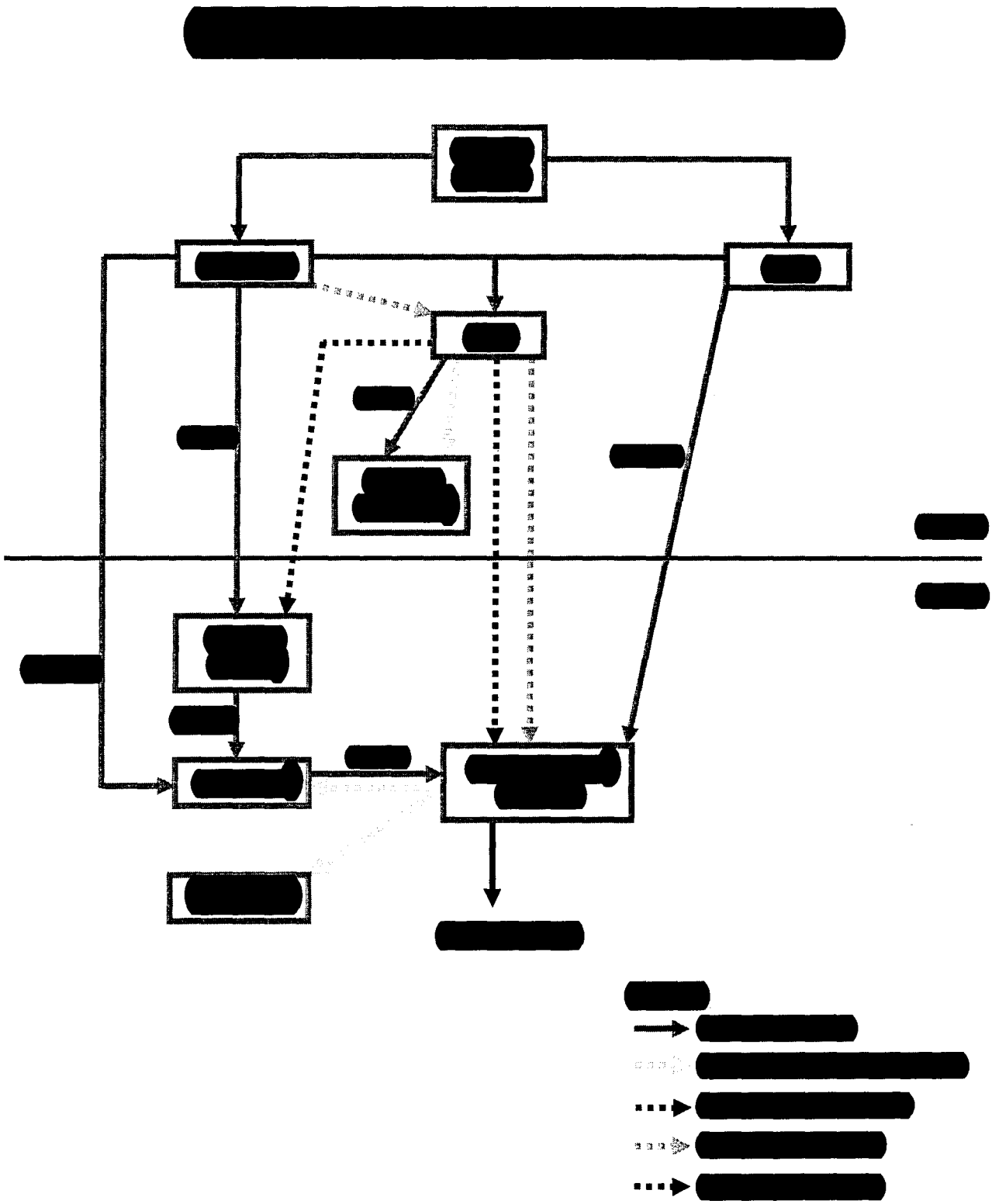
(a) Scope of Protection

530. The Tribunal must now address whether the claims in these proceedings implicate assets that qualify as investments which are protected against divestment by the France-Poland BIT. For these purposes, the definitional provisions in Article 1 of the BIT must be read in the context of the relationship between "investor" and "investment" set forth in BIT Article 5(2).

531. One contracting state shall not take expropriation or nationalization measures which would have the effect of divesting "investors of the other Party" of investments "belonging to them [*i.e.*, to investors of the other contracting state]" when such investments are located "in its [*i.e.*, the allegedly expropriating state's] territory or maritime areas."

532. The expression "belonging to" in the context of this BIT would most reasonably connote ownership and a sense of rightful entitlement. Notably, the BIT contains no qualification of "belonging to" that would preclude an ownership interest that might be partial or indirect.





[redacted]

[1002] The Tribunal has generally used the English translation of the France-Poland BIT found in the United Nations Treaty Series (UNTS) submitted as Exhibit R-001. [redacted]

[1007] [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

[redacted]

1004 [redacted]

[redacted]

[1005] Reply, para. 173; *see also* Statement of Claim, Appendix 2.

[1006] Reply, para. 173.

[1007] [redacted]

[redacted]

C. DIVESTMENT

1. Treaty Framework

563. Article 5(2) of the France-Poland BIT establishes a series of interconnected mandates for this Tribunal's determinations on liability and quantum. The first subparagraph of section (2) prohibits divestment of investments that "belong to" investors, except for reasons of public necessity and on condition that these measures are not discriminatory or contrary to a specific undertaking.

564. Significantly, however, the second subparagraph of Article 5(2) provides that "any" divestment measures (whether illicit or not) shall give rise to prompt and adequate compensation.[1009] The provision does not distinguish between whether divestment measures prove legitimate or not pursuant to the criteria of the first subparagraph, but states simply as follows:

> Any divestment measures that may be taken shall give rise to the payment of prompt and adequate compensation, the amount of which shall correspond to the real value of the investments in question on the day before the measures are taken or made known to the public.

565. The French and Polish texts of the second paragraph accord with the English translation cited above. The French speaks of "les mesures de dépossession qui pourraient être prises."

566. The English translation of the Polish text provided by the Respondent as Exhibit R-007 uses the word "any" to render that phrase as "The application of any expropriation measures shall entail the prompt payment," translating from the Polish "Zastosowanie środków wywlaszczeniowych powinno pociągnąć za sobą niezwłoczną wyplatę wlaściwego odszkodowania." Consequently, as a preliminary matter the Tribunal must determine the

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[1009] As mentioned earlier the Tribunal has, with one exception noted *supra*, used the English version of the France-Poland BIT published in the UN Treaty Series, submitted as Exhibit R-001.

nature of divestment measures, and whether or not such measures violated the first subparagraph of Article 5(2).

567. If divestment has occurred, then the Tribunal is called to fix compensation for the "real value" of the investment. The Tribunal must also determine whether violations occurred with respect to the first subparagraph, and if so what consequences might follow beyond the requirement to pay for the "real value" of the investment.

568. Evaluating Poland's actions in light of its Treaty obligations with respect to divestment, the Tribunal must accord due deference to the decisions of specialized Polish administrators interpreting and applying laws and regulations governing their area of competence. In doing so, however, the Tribunal will also consider the manner in which these decisions were taken and their effect on the Claimants' investments.

2. Exercise of Administrative Power

(1) Nature of Divestment

569. The Tribunal agrees with the Parties that a host state's regulatory and/or administrative actions must be taken (i) in good faith, (ii) for a public purpose, (iii) in a way proportional to that purpose, and (iv) in a non-discriminatory manner.[1010]

570. Stated from a somewhat different perspective, the Respondent's denial of marketing authorisations would divest the Claimants of their property, giving rise to a requirement of compensation under the BIT, if Poland exercised its administrative and regulatory powers in bad faith, for some non-public purpose, or in a fashion that was either discriminatory or lacking in proportionality between the public purpose and the actions taken.

571. The standard set forth above relates to "any" divestment as articulated in the second subparagraph of Article 5(2) of the BIT, and is not specific to the illicit dispossession covered in the first subparagraph of that provision.

572. The Tribunal is well aware that any divestment as such must be followed by compensation pursuant to the second subparagraph of Article 5(2), regardless of whether the divestment entails illicit actions covered by the first subparagraph of that section which prohibits certain types of expropriations.

573. The Tribunal must take BIT Article 5(2) as drafted. One portion of that provision imposes a negative rule that expropriation or nationalization measures not be taken except for reasons of public necessity and provided that such measures are not discriminatory or contrary to a

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[1010] *Compare* Statement of Claim, para. 215 *and* Reply, para. 283 *with* Statement of Defence, para. 490.

particular obligation. Another portion of the provision imposes a positive mandate that any divestment shall give rise to adequate compensation.

574. For reasons set forth below, the Tribunal has found a divestment.

575. Moreover, the divestment violates the mandates of the first subparagraph. Not only was the refusal of authorisation discriminatory, but the regulatory measures were disproportionate in nature and thus not a matter of public necessity. However, the Tribunal does not find that the divestment calls for damages beyond those set out in Article 5(2) of the Treaty in the form of "real value" compensation.

576. In this connection, the Tribunal notes that indirect expropriation, at issue in this case, implicates a State's substantial interference with an investor's rights. Such interference must be significant, even if not complete, in the sense of depriving the investor of its ability to benefit from the relevant asset.

577. The Tribunal also stresses that the terms of the France-Poland BIT do not require that dispossession be permanent in the sense of continuing *ad infinitum*, although deprivation must possess a character which is more than transitory. [redacted]

*(2) **Burden of Proof***

578. The Parties disagree on who bears the burden of proof on whether Poland exercised its regulatory and administrative powers in a legitimate fashion.

579. The Claimants point to Article 24(1) of the UNCITRAL Rules which provides: "Each party shall have the burden of proving the facts relied on to support his claim or defence." The Claimants view a plea of valid exercise of regulatory powers as an "affirmative defense," for which Poland bears the burden of proof.

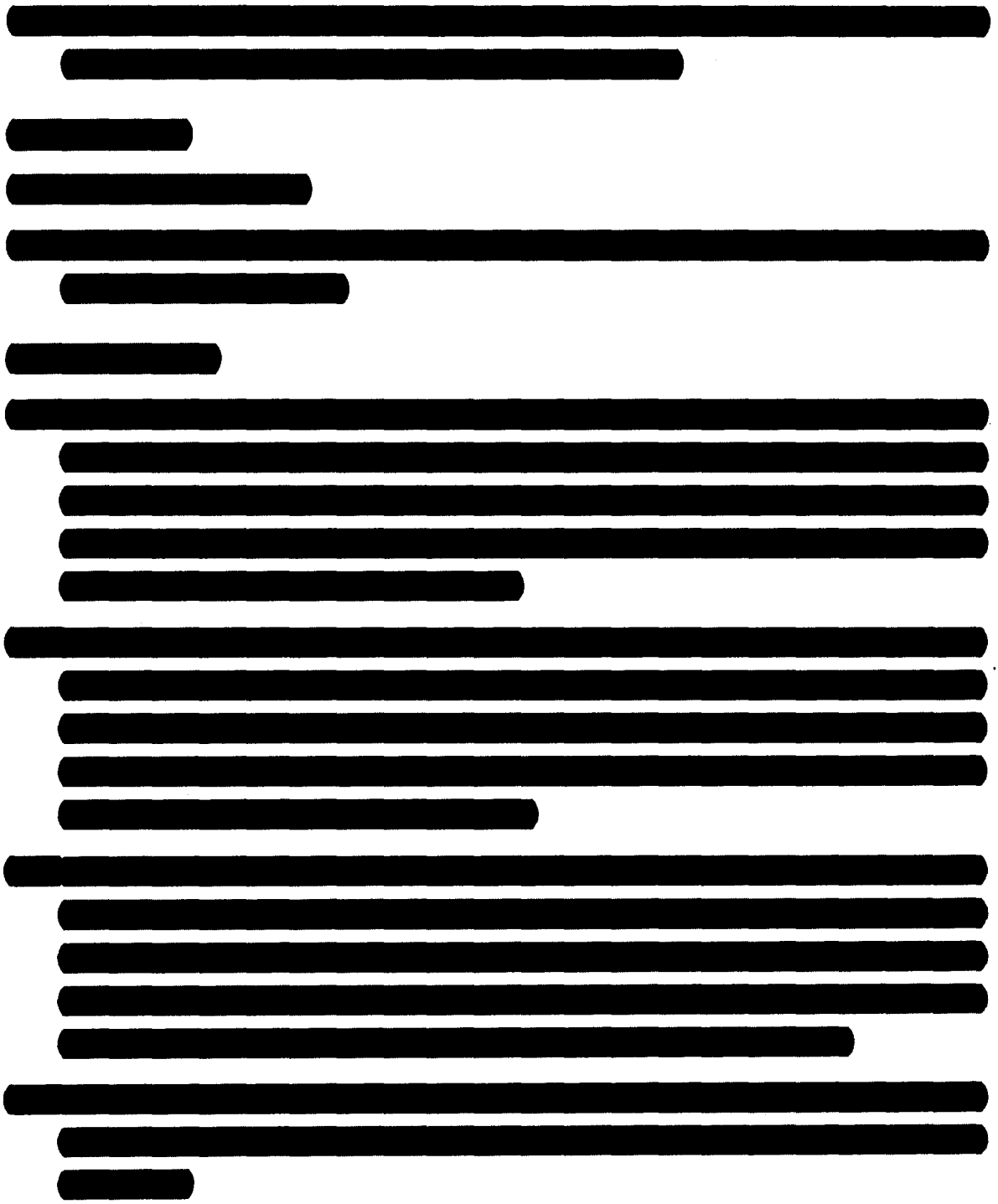
580. By contrast, Poland argues that its sole duty is to show that there is a reasonable connection between its actions and a legitimate policy objective.

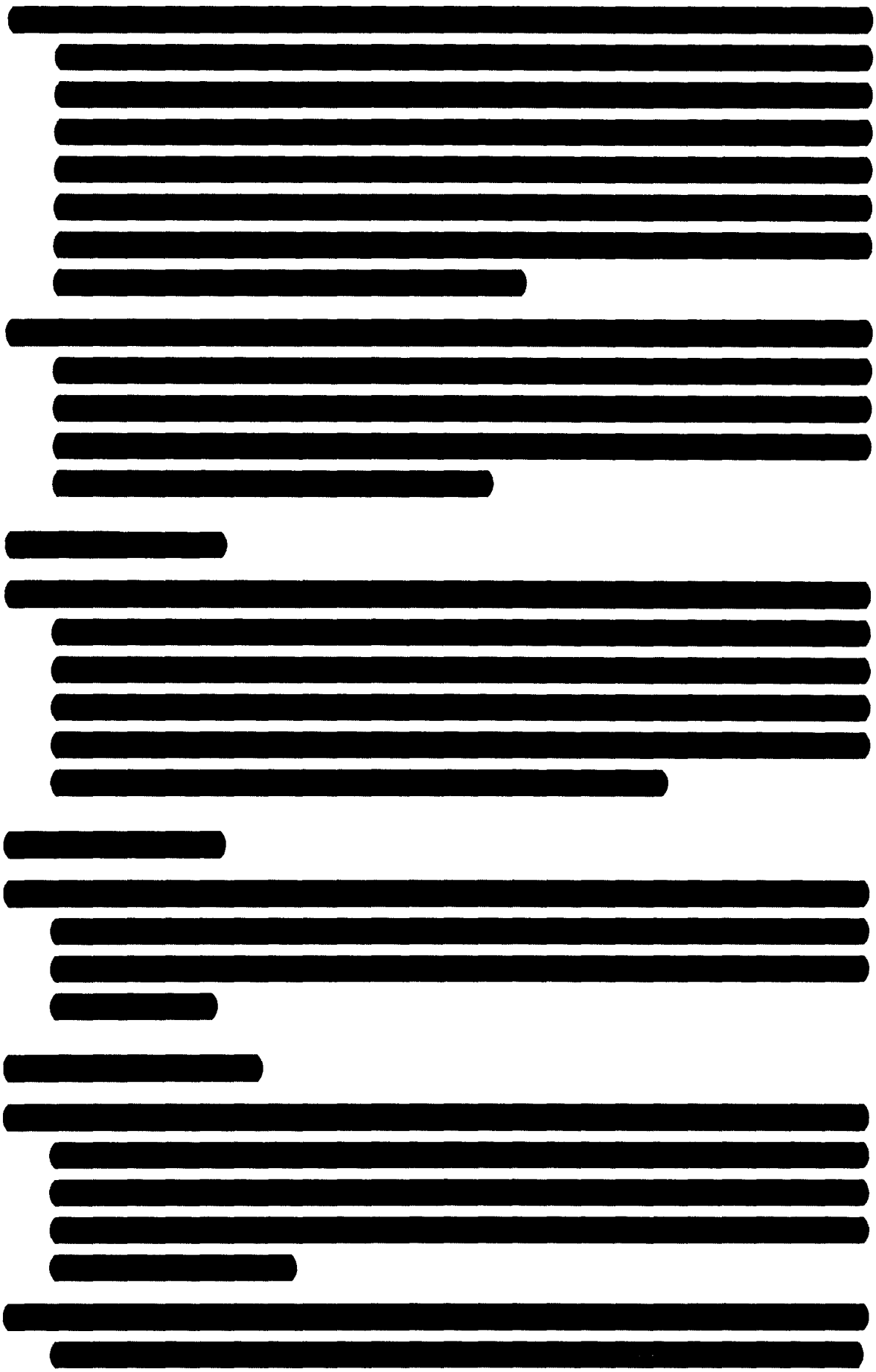
581. The Tribunal takes an approach that includes elements of each perspective.

582. Poland has come forward with *prima facie* justifications for rejecting the Claimants' applications for marketing authorisations. According to Poland, the rejection derived from provisions of, and policies associated with, the Polish Pharmaceutical Law and EU legislation.

583. In light of such explanations, it would be unreasonable to demand that Poland "prove the negative" in the sense of demonstrating an absence of bad faith and discrimination, or the lack of disproportionateness in the measures taken.

584. Thus, the burden then falls onto the Claimants to show that Poland's regulatory actions were inconsistent with a legitimate exercise of Poland's police powers. If the Claimants produce sufficient evidence for such a showing, the burden shifts to Poland to rebut it.





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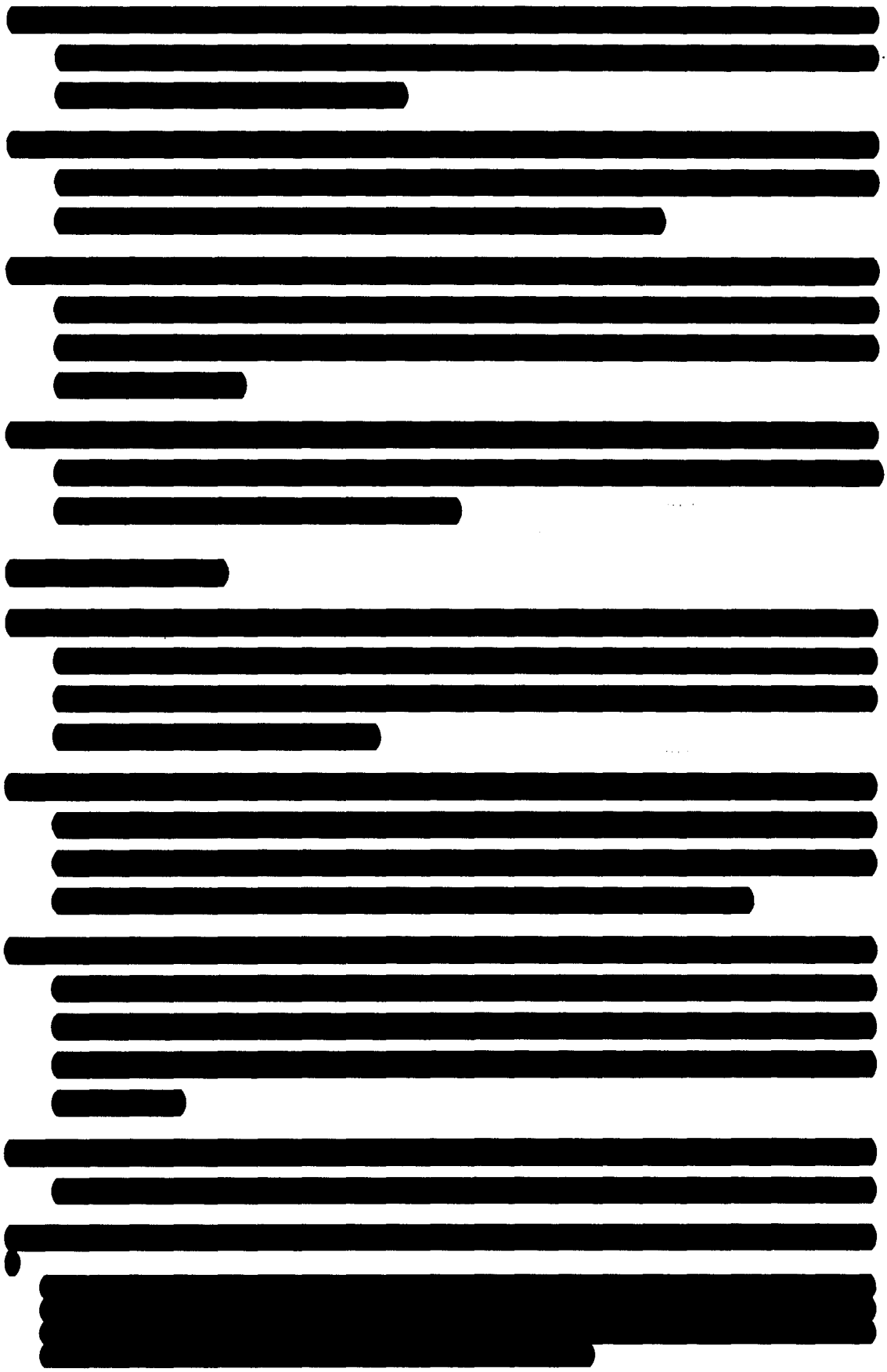
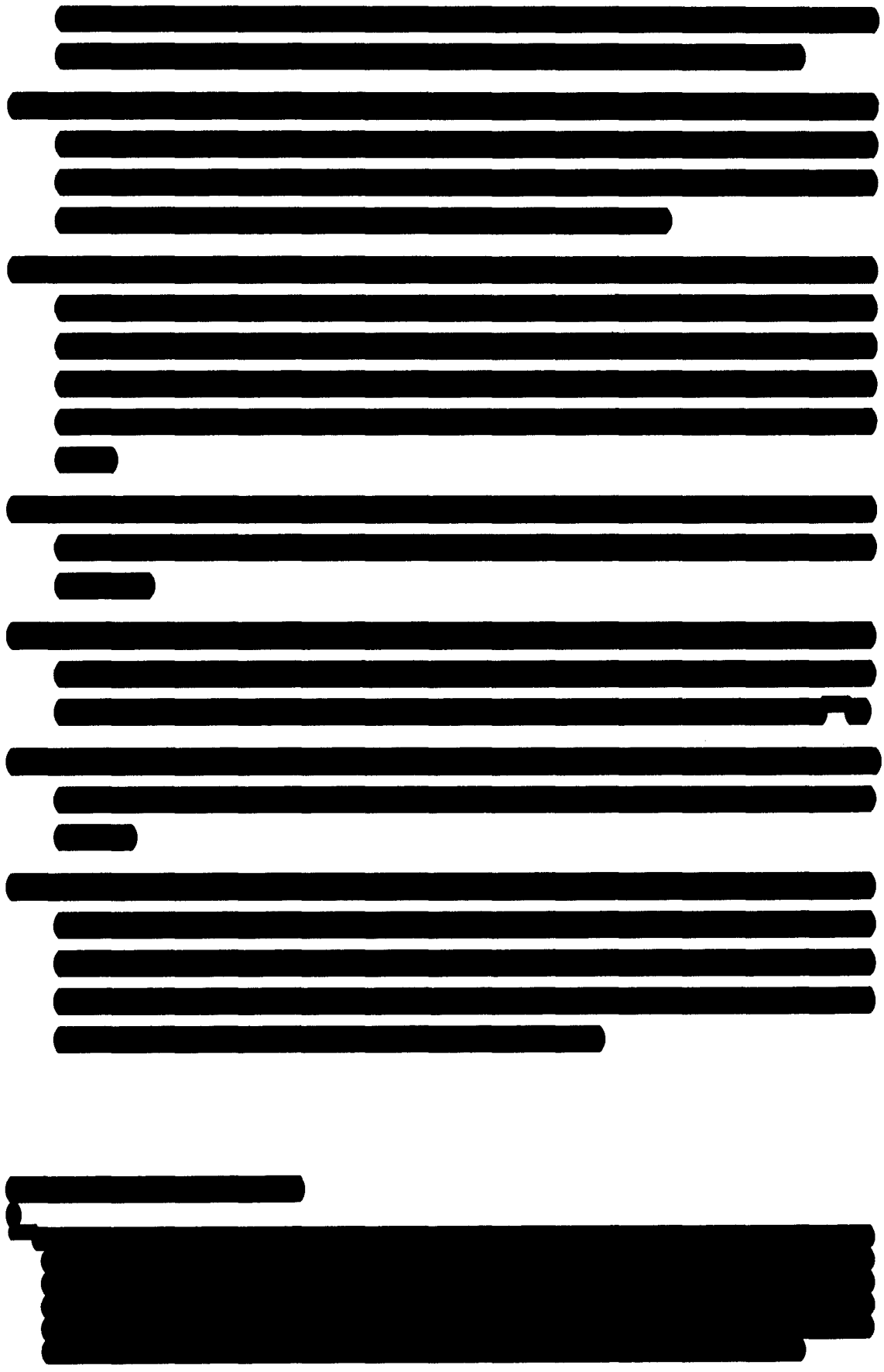
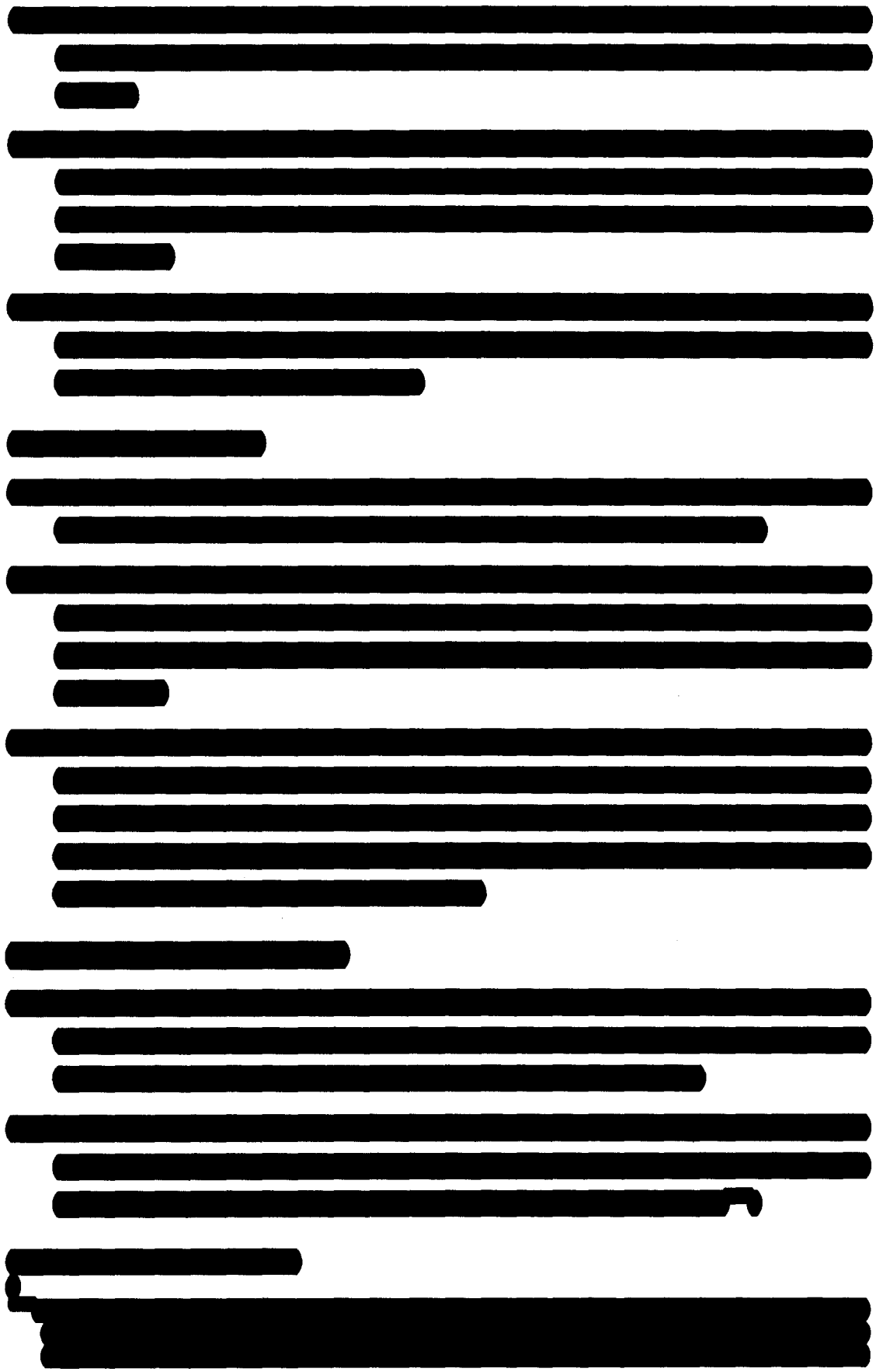
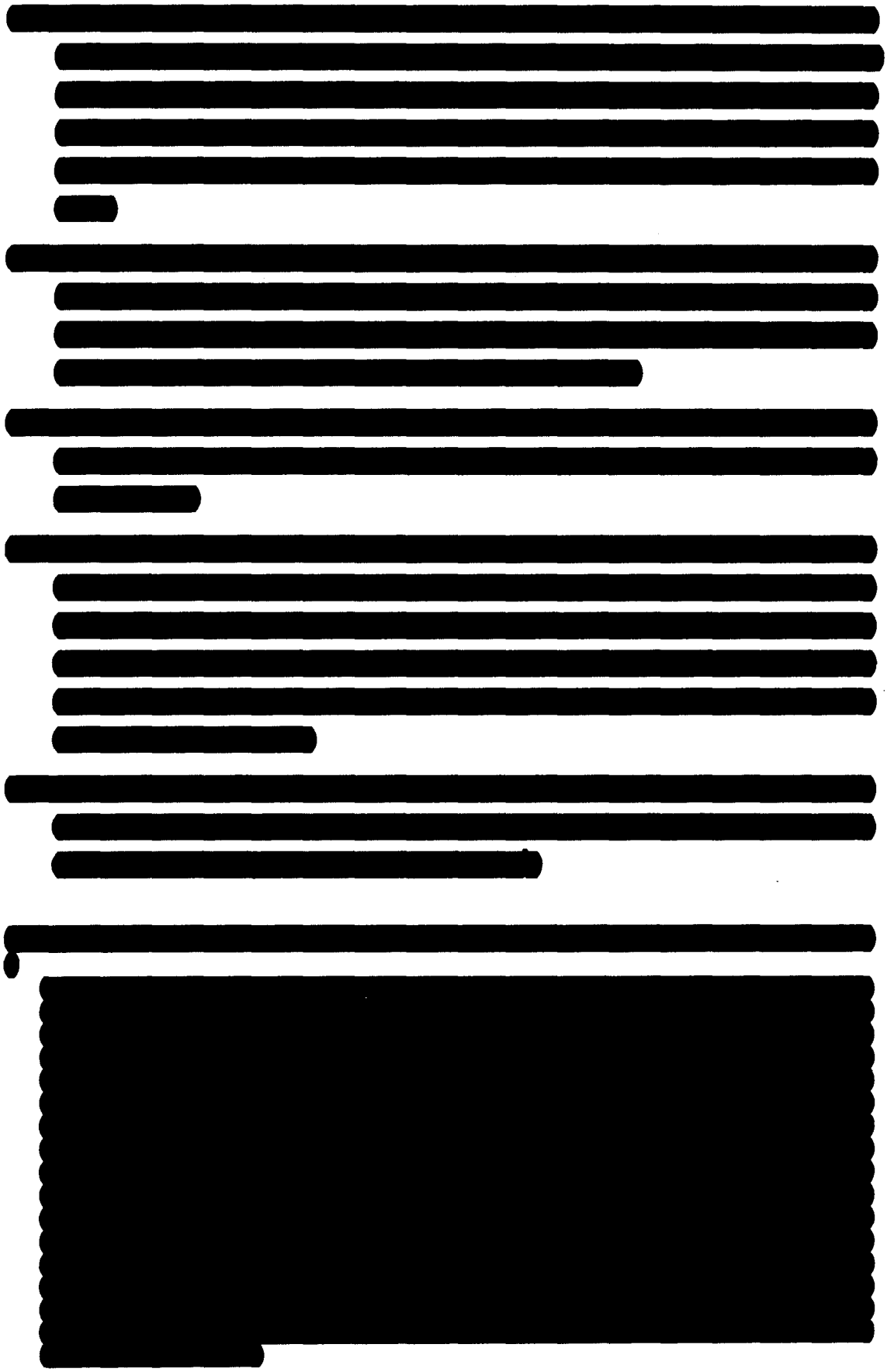
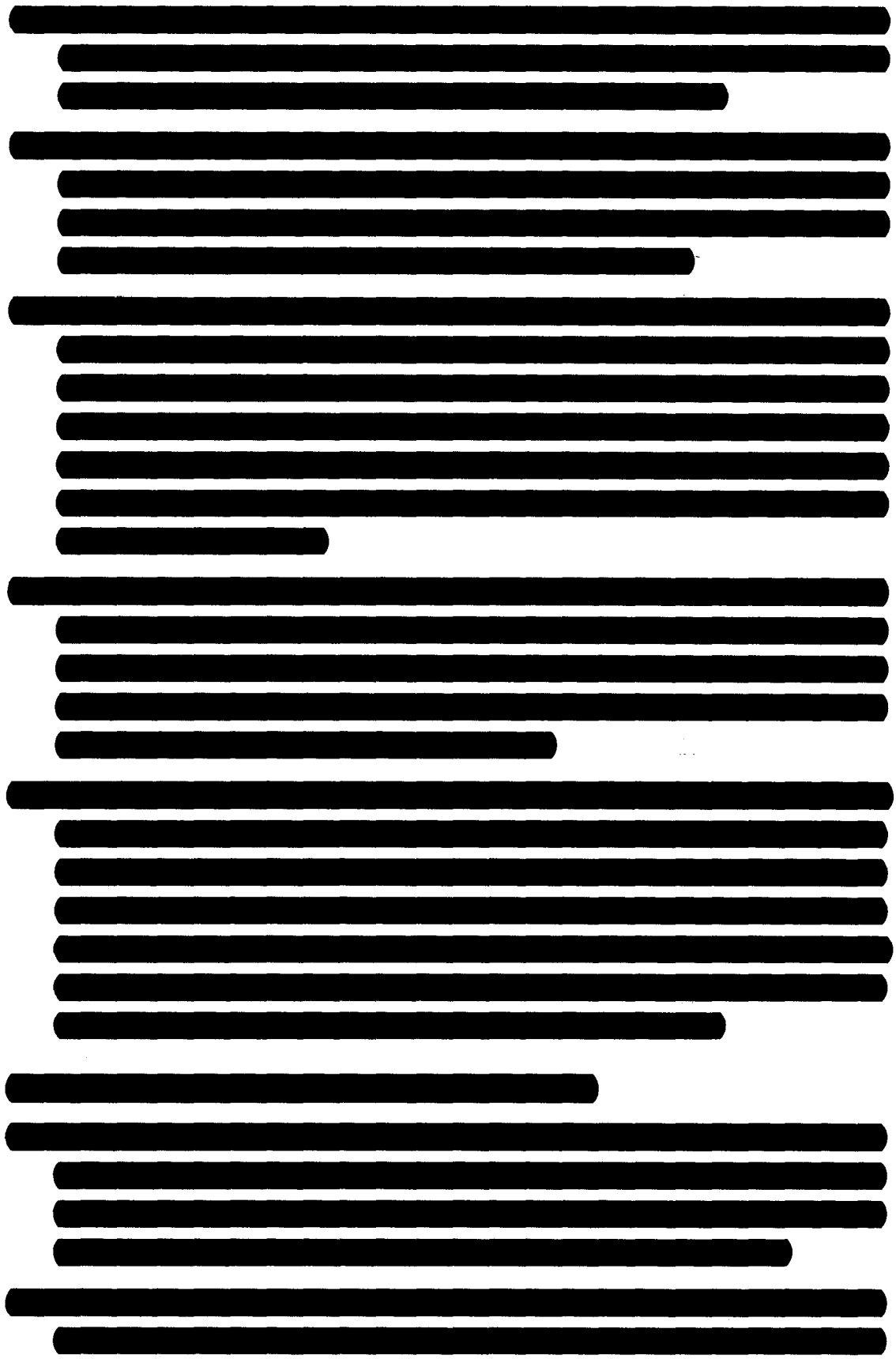
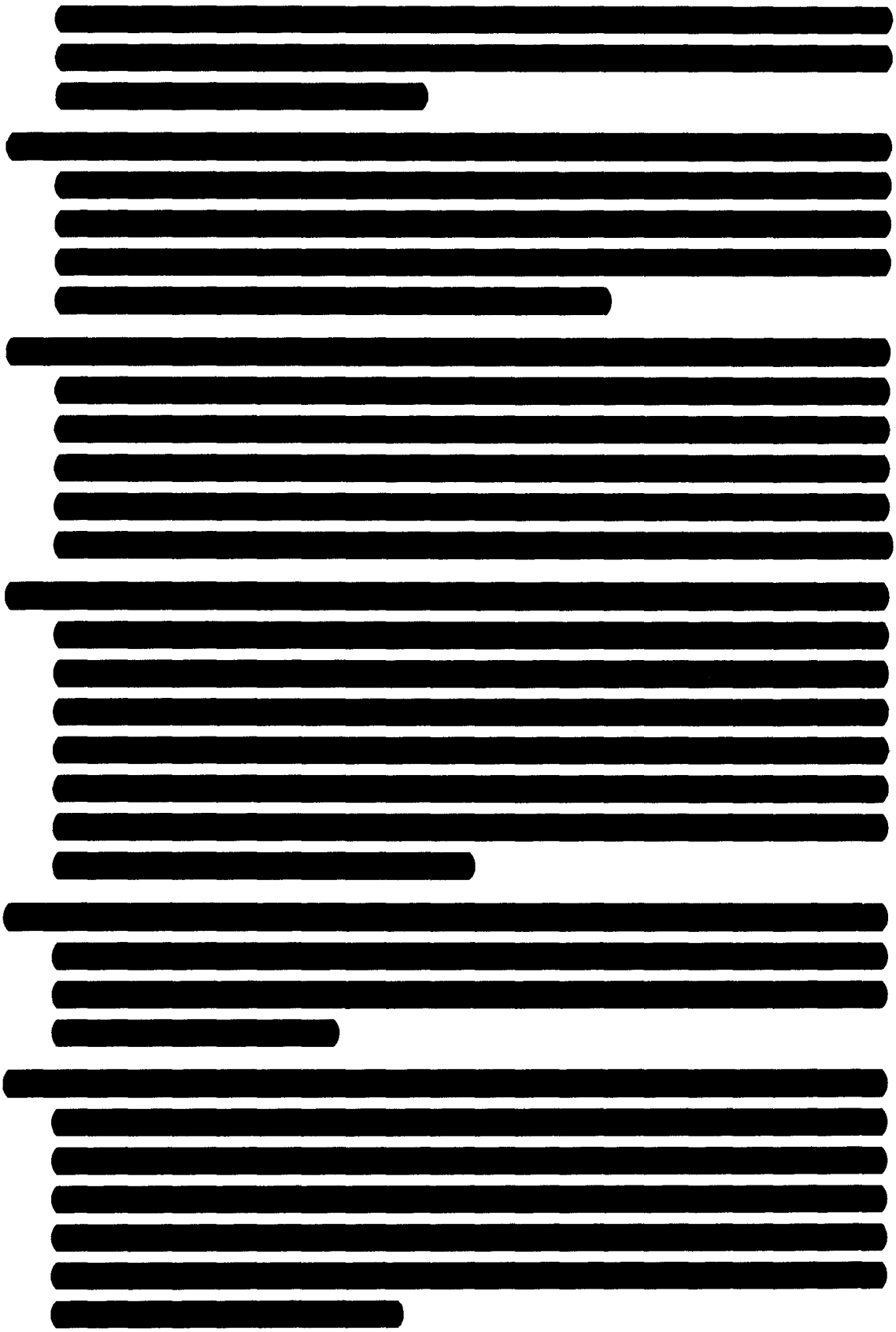












D. DAMAGES

1. Legal Standard

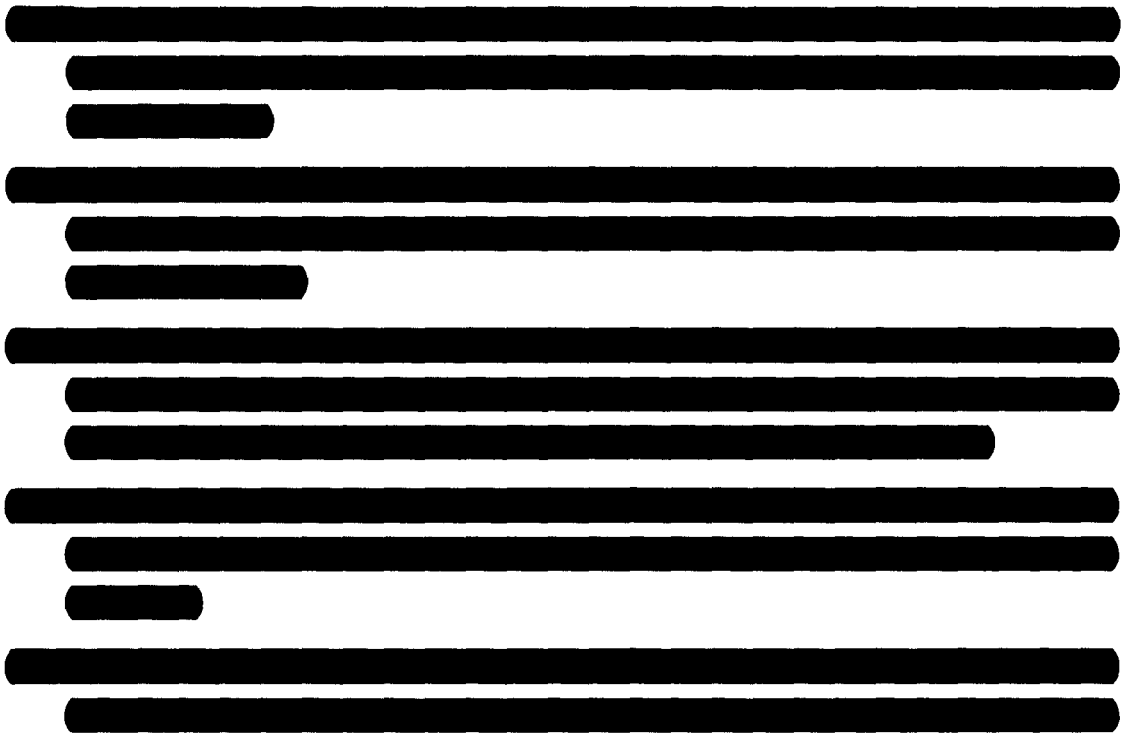
642. Given the Tribunal's finding that Poland has not engaged in bad faith behaviour in a way that would require damages beyond the Treaty standard, the Tribunal must simply apply the standard of compensation for the divestment of "any" investment under BIT Article 5(2).

643. According to that provision, divestment shall give rise to payment of "prompt and adequate compensation" corresponding to the "real value" of the divested investments on the day before the measures were taken or made public.

644. As noted earlier, the Tribunal interprets the second subparagraph of BIT Article 5(2) as setting the standard of compensation for any divestment, not just what might be called "permitted" expropriations which did not violate the earlier prohibitions on discrimination, breach of specific undertakings, and reasons of public necessity.

645. Although no single interpretation may prove entirely satisfactory under all circumstances, the reading of the Treaty that comports with common sense would provide a floor of "real value" compensation for all divestments (not just legitimate takings), allowing tribunals discretion to impose additional sanctions to punish Treaty violations of particular seriousness, such as discrimination or breach of specific undertakings.

2. Valuation



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1014 [redacted]

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3. Pre-Award Interest

663. Article 5(2) of the BIT provides that compensation "shall yield, up to the date of payment, interest calculated on the basis of the appropriate rate of interest in force at the time of divestment."

664. The Tribunal is mindful of the last sentence of Article 5(2) ("interest in force at the time of divestment"). The connotation of the phrase "rate of interest in force" is that the Treaty looks to some rate external to the particular capital costs of the Parties' own transaction. In searching for an appropriate rate, the Tribunal finds guidance in the 12-month EURIBOR.

665. The Tribunal will compound interest on an annual basis using the 12-month EURIBOR rate which, as mandated in the Treaty, was "in force at the time of the divestment," which is to

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1015 [redacted]

say, on 31 December 2008. Thus, the Tribunal applies the EURIBOR rate of 3.049 percent from the date of divestment until the date of the Award, yielding [redacted] in interest. This same interest rate will also apply to post-Award interest until the time of payment.

4. Tax Ramifications of Award

666. Although the Tribunal has considered the possible tax ramifications of this Award, it can find no reason to speculate on the appropriateness, one way or another, of any proposed "gross-up" to take into account potential tax liability, whether in Poland or in France. The ultimate tax treatment of an award representing the "real value" of an investment must be addressed by the fiscal authorities in the investor's home jurisdiction as well as the host state.

5. Post-Award Interest

667. BIT Article 5(2) provides that compensation "shall yield, up to the date of payment, interest calculated on the basis of the appropriate rate of interest in force at the time of the dispossession."

668. Thus, from the date of the Award, until fully paid, that amount shall be subject to annual compound interest at a rate equal to the 12-month EURIBOR in force on 31 December 2008, namely 3.049 percent.

E. COSTS

669. The Tribunal finds that both sides have presented some meritorious arguments, each side winning on some issues while losing on others.

670. Many of the arguments were finely balanced. Neither side advanced its case in bad faith. Neither position was clearly untenable.

671. Counsel for both sides behaved in ways which furthered procedural efficiency, and no abuse of process was present. Counsel for all Parties evidenced a high degree of efficiency and professionalism in pleading their respective cases.

672. Consequently, the Tribunal concludes that each Party shall bear its own attorneys' fees and related other costs, and that the costs of arbitration, including the fees of the arbitrators and the administrative expenses of the PCA, shall be divided on an equal (50/50) basis.

673. The total costs of the arbitration, including arbitrators' fees and expenses, as well as PCA administrative expenses, are set at [redacted]

VIII. DISPOSITION

674. The Tribunal has subject-matter jurisdiction only over claims of expropriation under Article 5(2) of the Treaty.

675. [redacted]

676. [redacted]

678. Each Party will bear its own legal costs and a half share of the arbitrators' and PCA fees.

679. [redacted]

The Hague, The Netherlands
Date: 14 February 2012

Dr. Bernard Hanotiau	Professor William W. Park	The Honourable Marc Lalonde