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# *Takeaways from Recent Implementation of China's Patent Linkage System*

By Bruce M. Wexler, Mi Zhou & Mark Russell Sperling

China has been reported to be the second largest biopharmaceutical market in the world.[1] In recent years, China has seen rapid growth in efforts at domestic drug innovation and in international collaborations.[2] Seeking to further promote innovation and accelerate growth, China has initiated a series of regulatory and patent reforms in the drug industry, including developing a patent linkage system that draws from the U.S. Hatch-Waxman Act for the early resolution of drug patent disputes.[3] China's patent linkage system became effective on June 1, 2021.

Under China's patent linkage system, innovator drug companies can sue for patent disputes and apply for a preliminary injunction before generic and biosimilar drugs are launched. This new system can improve the innovator's ability to protect its market in China. This article provides an update on the recent implementation of China's patent linkage system and provides considerations for innovator drug companies.

## I. Relevant Legislative History

Since at least 2017, China has been evaluating a patent linkage system under which market authorization of competitor drugs and the resolution of related patent disputes would be coordinated.[4] On January 15, 2020, China agreed to provide a patent linkage system under the economic and trade agreement between the United States and China.[5] For more information on that previous development, please see our January 23, 2020 article here.

On October 17, 2020, China passed amendments to the patent law, which include provisions to provide a mechanism for the early resolution of drug patent disputes before the marketing approval of competitor drugs.[6] The amended Chinese patent law also delegated rule-making authority to China's National Medical Products Administration ("NMPA") and China's National Intellectual Property Administration ("CNIPA") to promulgate detailed implementation measures.[7] The amended Chinese patent law became effective on June 1, 2021.

To implement the amended patent law, over the past year, the NMPA, the CNIPA, and the Supreme People's Court of China released a series of proposed administrative and judicial guidelines regarding the patent linkage system. For more information on some of these developments, please see our October 5, 2020 article here.

## II. Recent Implementation Updates

Since June 1, 2021, China has taken additional steps to implement the patent linkage system, including (1) launching China's marketed drug patent information registration platform; (2) issuing interim implementation measures for the patent linkage system, as well as judicial and administrative guidelines for patent linkage cases; and (3) proposing special provisions on patent invalidation proceedings related to patent linkage cases.

### *A. China's Marketed Drug Patent Information Registration Platform*

On June 25, 2021, China launched the marketed drug patent information registration platform.[8] This platform publishes the listing of the innovators' patents covering both small molecule and biologic drugs in a manner similar to the U.S. FDA's database commonly known as the "Electronic Orange Book" for small molecule drugs.[9] The Chinese platform also publishes, within 10 days after the acceptance of the generic and biosimilar drug applications, patent certifications submitted by drug applicants, including the company names, the drug application numbers, and the certifications regarding each of the listed patents.[10] According to China's marketed drug patent information registration platform, there have already been several patent certifications submitted by generic drug applicants asserting that their proposed drugs do not fall within the scope of the listed patent claims.[11]

### *B. Interim Implementation Measures and Adjudication Guidelines*

On July 4, 2021, the NMPA and the CNIPA jointly released interim regulations, titled "Implementation Measures for a Mechanism for Early Resolution of Drug Patent Disputes (Trial)" ("Interim Implementation Measures").[12] On July 5, 2021, the Supreme People's Court of China released judicial guidelines, titled "Guidelines from the Supreme People's Court on Several Issues Regarding the Application of Law in Adjudicating Civil Patent Cases Relating to Drug Registration" ("SPC Judicial Guidelines"), and the CNIPA released guidelines for administrative adjudication, titled "Measures for Administrative Adjudication Concerning Early Resolution of Drug Patent Disputes" ("CNIPA Administrative Adjudication Guidelines").[13] The Interim Implementation Measures, the SPC Judicial Guidelines, and the CNIPA Administrative Adjudication Guidelines became effective on July 5, 2021 and govern the current implementation of China's patent linkage system. They are largely similar to the proposed regulations and guidelines released over the past year.[14]

In China, the same patent linkage system governs both small molecule and biologic drugs.[15] In contrast, in the U.S., the Hatch-Waxman Act governs small molecule drugs and biologics are subject to a different set of procedures and regulations under the Biologics Price Competition and Innovation Act ("BPCIA"). With regard to venue, China's patent linkage cases can be filed in court and in the CNIPA.[16] With regard to the subject matter of the proceeding, China's patent linkage cases only determine infringement issues and do not determine patent validity.[17] Patent invalidation requests are filed in the CNIPA with the right to appeal to the court and are bifurcated from patent linkage proceedings.[18]

If a patent is listed for the innovator drug, then generic and biosimilar drug applicants are required to submit a certification to the NMPA.[19] These certifications are similar to the patent certifications under the U.S. Hatch-Waxman Act for small molecule drugs and are described in further detail below. In China, a Category 4 Certification allows a generic or biosimilar drug company to challenge patent validity (Category 4.1) and/or infringement (Category 4.2) with respect to each listed patent.[20] If a generic or biosimilar applicant certifies that the proposed drug product does not fall within the scope of a listed patent (Category 4.2 Certification), it must provide the innovator with relevant technical specifications of the proposed drug product along with the patent certification.[21]

When an action is commenced under China's patent linkage system, a nine-month automatic stay of marketing approval of generic drugs will be entered.[22] While this is considerably shorter than the 30-month stay of generic drug approval typically available in the U.S., the relevant Chinese patent linkage proceedings also have a narrower field of inquiry that focuses only on infringement issues. Also, innovators may apply for a preliminary injunction in patent linkage litigation.[23] Regardless of these challenges, innovators will have to rely on patent exclusivity in China because the current system does not provide the type of regulatory data exclusivity rights for innovators available in the U.S. system.

To incentivize generics to seek early drug entry, China provides a one-year market exclusivity for a generic drug company that is the first to invalidate the innovator's patent(s) and the first that markets the generic drug.[24] This differs from the U.S. system in that it is longer (the Hatch-Waxman Act grants only 180 days of exclusivity) and in that it may only be shared among multiple generic drug companies in a limited circumstance when they jointly invalidated the patents.[25]

Further, an innovator drug company that does not prevail in a Chinese patent linkage proceeding may be liable for compensatory damages if the court finds that it knew or should have known that an asserted patent should be declared invalid or that the proposed competitor drug product does not fall within the asserted patent.[26]

Additional key features of China's patent linkage system, as well as comparisons with the U.S. Hatch-Waxman and BPCIA systems, are in the table below.

| Key Provisions | China's Patent Linkage System | U.S. Hatch-Waxman and BPCIA Systems |
|---|---|---|
| Types of patents for listing and dispute resolution | For small molecule drugs, the holder of a drug application may submit patents covering (1) the active ingredient; (2) pharmaceutical composition comprising the active ingredient; and (3) medical use consistent with the approved indication(s) or primary treatment effect(s) in the drug label.[27]<br><br>For biologic drugs, the holder of a drug application may submit patents (1) covering biological sequences; and (2) medical use consistent with the approved indication(s) or primary treatment effect(s) in the drug label.[28]<br><br>Patents on intermediates, metabolites, crystal forms, manufacturing processes or analytic methods may not be listed.[29] | For small molecule drugs, a drug company that submits a new drug application ("NDA") must generally inform the FDA of patents covering (1) the active ingredient; (2) the drug product (formulation and composition); and (3) method of treatment for which approval is sought or has been granted.[30]<br><br>For biologic drugs, a reference product sponsor ("RPS") may list in the "patent dance" patents for which a claim of patent infringement can be reasonably asserted covering, for example, the biological active ingredient, formulation, method of treatment, and manufacturing process.[31] |

| Key Provisions | China's Patent Linkage System | U.S. Hatch-Waxman and BPCIA Systems |
|---|---|---|
| Drug patent database | For small molecule and biologic drugs, drug patent information is published on China's marketed drug patent information registration platform.[32] | For small molecule drugs, drug patent information is published on an FDA website commonly known as the "Electronic Orange Book."[33]<br><br>For biologic drugs, the BPCIA does not rely on a pre-published patent list. Drug patent information may be included in an FDA website commonly known as the "Electronic Purple Book."[34] |
| Patent certifications to drug administrative agency | For small molecule and biologic drugs, a competitor drug applicant shall make one of the following patent certifications, as applicable and with regard to each listed patent:<br>(1) no relevant patent information is listed on China's marketed drug patent information registration platform;<br>(2) the patent has expired or been declared invalid, or the competitor drug applicant has obtained a license to practice the patent;<br>(3) competitor drug will not be launched before expiration of the patent;<br>(4.1) the patent should be declared invalid; or<br>(4.2) the proposed drug product does not fall within the patent protection.[35] | For small molecule drugs, a generic drug company that submits an abbreviated new drug application ("ANDA") shall make one of the following patent certifications, as applicable and with regard to each listed patent:<br>(I) patent information on the innovator drug has not been filed;<br>(II) the patent has expired;<br>(III) the date on which the patent will expire; or<br>(IV) the patent is invalid, unenforceable and/or not infringed.[36]<br><br>For biologic drugs, the pre-suit disclosure of patents and contentions may follow the multi-phase procedures known as the "patent dance."[37] |

| Key Provisions | China's Patent Linkage System | U.S. Hatch-Waxman and BPCIA Systems |
|---|---|---|
| Notification materials and process | For small molecule and biologic drugs, a competitor drug applicant shall send the patent certification and the certification basis to the NDA holder.[38]<br><br>If a competitor drug applicant certifies that the proposed drug product does not fall within the patent protection, the certification basis shall include (1) a chart comparing the technical specification of the proposed drug product and the relevant patent claim(s), and (2) related technical materials.[39]<br><br>China's marketed drug patent information registration platform publishes the filing of ANDA applications and patent certifications.[40] | For small molecule drugs, an ANDA filer that makes a Paragraph IV certification shall send a notice letter to the NDA holder and patent owner detailing the factual and legal bases of its certification.[41] The notice is accompanied by an offer of confidential access to portions of the ANDA, which often involves a negotiation process to potentially obtain the ANDA or parts of it.[42]<br><br>For biologic drugs, the pre-suit disclosure of patent lists and patent positions may follow the multi-phase procedures known as the "patent dance."[43] |
| Subject matter of patent proceedings | Whether or not the proposed drug product falls within the protection of the listed patent(s)[44] | Typical aspects of patent infringement and validity, with damages claims generally prohibited in the absence of a commercial launch[45] |
| Deadline to commence patent proceedings | For small molecule and biologic drugs, within 45 days of the publication of the filing of the competitor drug application by the Chinese drug administration[46] | For small molecule drugs, within 45 days of the receipt of a notice letter from an ANDA filer in order to obtain the automatic stay if available[47]<br><br>For biologic drugs, the "patent dance," if followed, would govern timing for disclosures and filing of suit.[48] |
| Venue for patent proceedings | Beijing Intellectual Property Court or CNIPA[49] | U.S. district court[50] |

| Key Provisions | China's Patent Linkage System | U.S. Hatch-Waxman and BPCIA Systems |
|---|---|---|
| Civil action by generic drug applicants to obtain certainty | If the patent owner or an interested party does not timely commence a patent linkage proceeding, a generic drug applicant may file suit or request an administrative ruling to confirm that the proposed drug product does not fall within the listed patent(s).[51] | For small molecule drugs, the ANDA filer may seek a declaratory judgment of noninfringement/invalidity if the patentee does not sue within the 45-day window.[52] |
| Stay of marketing approval of generic drug applications pending litigation | For small molecule drugs, up to one nine-month automatic stay, if a patent linkage proceeding is timely brought.[53]<br><br>For biologic drugs, there is no automatic litigation stay.[54] | For small molecule drugs, generally, up to one 30-month automatic stay, if a patent infringement suit is timely brought.[55]<br><br>For biologic drugs, there is no automatic stay, but the notice of commercial marketing is a prerequisite to commercial launch.[56] |
| Preliminary injunction | During a patent linkage litigation, the patent owner or an interested party may request that the court enjoin patent infringement by the competitor drug applicant.[57] | Preliminary injunctions, though available and granted, are generally considered an extraordinary remedy.[58] |
| Exclusivity for generic drugs | For small drugs, a generic drug applicant that is the first to (1) succeed in the patent challenge, and (2) obtain approval and market the drug is eligible for a one-year exclusivity, provided that the exclusivity does not exceed the term(s) of the patent(s) challenged.[59]<br><br>Successful patent challenge means that a generic drug applicant submitted Category 4 certification(s), and according to the invalidity declaration, the relevant patent is invalidated, thereby resulting in the marketing authorization of the generic drug.[60] | For small molecule drugs, and subject to a complex set of rules and regulations, each ANDA filer that is the first to file an ANDA containing a qualifying Paragraph IV certification with respect to a timely listed patent may be eligible for 180-day exclusivity.[61] |

| Key Provisions | China's Patent Linkage System | U.S. Hatch-Waxman and BPCIA Systems |
|---|---|---|
| Remedies for improper litigations | If the patent owner or an interested party commences a patent linkage proceeding and knew or should have known that an asserted patent shall be declared invalid or that the proposed competitor drug product does not fall within the patent protection, the competitor drug applicant may file suit in the Beijing Intellectual Property Court for compensatory damages.[62] | Award of reasonable attorney fees to the prevailing party in exceptional cases.[63] |

### *C. Proposed Special Provisions on Patent Invalidation Proceedings Related to Patent Linkage Cases*

On August 3, 2021, the CNIPA released draft amendments to the patent examination guidelines, which include proposed special provisions regarding patent invalidation proceedings related to patent linkage cases.[64] These proposed special provisions only apply to patent invalidation requests filed by drug applicants that submitted a Category 4 certification challenging the validity of a patent listed on China's drug patent information registration platform.[65] Comments are being solicited for the draft amendments through September 22, 2021.[66]

These proposed special provisions seek to coordinate CNIPA's review of multiple invalidation requests that are filed against the same patent involved in patent linkage cases, which may become a common occurrence. Examinations of multiple invalidation requests filed against the same patent will be docketed based on the filing date of each request.[67] If a patentee amends the claims during an earlier proceeding and the amended claims are held valid, the CNIPA may determine patent validity based on these amended claims in a subsequent proceeding.[68] If the CNIPA determines that at least one claim of a patent is invalid, then subsequent proceedings concerning the same patent will be stayed until the earlier proceeding becomes final, *i.e.*, after the expiration of the deadline to appeal or the conclusion of final appeal.[69]

These proposed special provisions would also establish a mechanism for the court or the NMPA to request the status of invalidity proceedings before the CNIPA.[70] If the court or NMPA requests the case status, the CNIPA will also be required to provide them with the decision at the conclusion of the invalidation proceeding.[71]

## III. Practical Considerations Going Forward

Under China's new patent linkage system, innovator drug companies can now sue for possible infringement before the marketing and sale of generic and biosimilar drugs. This procedure was not previously available in China. The nine-month automatic stay established by China's patent linkage system is helpful but will likely not be long enough for a final decision in many cases. To address potential at-risk launches from generic drug companies, innovators may need to consider moving for a preliminary injunction at the appropriate time. Of course, it will be critical to have on-the-ground advice from

Chinese patent counsel about legal and practical strategies in any given situation. Coordination with other jurisdictions, especially important markets such as the U.S., may also be important.

Due to the relatively short automatic stay, it can be important for innovators to establish a strong showing of infringement as soon as possible, particularly if a preliminary injunction may need to be requested. Thus, innovators should consider front-loading as much of the infringement analysis as possible during pre-suit analyses. Depending on the subject matter and issues in each case, it may also be helpful to engage experts and testing laboratories in advance. Innovators should also ensure that generic or biosimilar applicants produce all necessary technical information needed to prove infringement. As in the U.S. Hatch-Waxman and biosimilar litigations, disputes regarding the proper scope of the production can arise and innovators should be prepared to address them with the assistance of their counsel in China.

Innovator drug companies should also expect vigorous invalidity attacks as generic drug companies seek to take advantage of the one-year market exclusivity. Generic drug applicants will likely be more incentivized to dream up invalidity attacks and devote greater resources and commitment toward them. As a result, innovator drug companies should ensure that the pre-suit period is also used to anticipate possible invalidity attacks and be prepared to deal with them.

Innovator drug companies marketing drugs internationally should also prepare for parallel patent challenges across multiple jurisdictions, including, more and more, China. Litigations in China and other countries, such as the U.S., may involve patents in the same families and may even concern the same generic or biosimilar applicants. Even though the legal standards are different, the patents and their prosecution records may be different, and there may be differences in the subject matter at issue, potentially making the proceedings not relevant to one another, innovators may still wish to coordinate with regard to issues such as infringement theories, interpretations of significant terms, characterizations of the prior art, and fact and expert testimony, out of an abundance of caution.

As China continues to reform its drug patent law, interested drug companies should stay current on the relevant developments and quickly adjust their strategies. Interested companies should consider submitting comments to proposed administrative and judicial guidelines on the new patent linkage system that are continuing to be released. Drug companies should also monitor any potential policy reform on regulatory data rights protection in China and consider advocating the importance of such protection in promoting new drug development. Staying current on these developments is critical for legal success in China's rapidly evolving drug patent space.

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*If you have any questions concerning these developing issues, please do not hesitate to contact any of the following Paul Hastings New York lawyers:*


Bruce M. Wexler
1.212.318.6020
brucewexler@paulhastings.com

Mi Zhou
1.212.318.6809
mizhou@paulhastings.com

Mark Russell Sperling
1.212.318.6738
marksperling@paulhastings.com

[1] *E.g.*, Outlook on Biopharma Innovation Trends in China, Deloitte (July 2021), at 40.

[2] *Id.*; THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA, 2020 Annual Drug Review Report (June 21, 2021).

[3] *See, e.g.*, What Drug Companies Should Be Thinking About After the U.S.-China Trade Deal (Jan. 23, 2020), https://www.paulhastings.com/insights/client-alerts/what-drug-companies-should-be-thinking-about-after-the-us-china-trade-deal; Outlook on Biopharma Innovation Trends in China, Deloitte (July 2021), at 40-44.

[4] THE STATE FOOD AND DRUG ADMINISTRATION OF CHINA, Policies Regarding the Promotion and Protection of Innovators' Rights in Pharmaceutical Products and Medical Devices (Draft for Public Comment) (May 12, 2017).

[5] Economic and Trade Agreement Between the Government of the United States of America and the Government of the People's Republic of China, at Art. 1.11 (Jan. 15, 2020).

[6] China's Patent Law (Oct. 15, 2020), at Art. 76.

[7] *Id.*

[8] China's Marketed Drug Patent Information Registration Platform, https://zldj.cde.org.cn/home.

[9] In addition to small molecule and biologic drugs, China's marketed drug patent information registration platform also publishes patent listings and patent certifications concerning traditional Chinese medicine.

[10] CHINA'S NATIONAL MEDICAL PRODUCTS ADMINISTRATION ("NMPA") AND CHINA'S NATIONAL INTELLECTUAL PROPERTY ADMINISTRATION ("CNIPA"), Implementation Measures for a Mechanism for Early Resolution of Drug Patent Disputes (Trial) (July 4, 2021) ("Interim Implementation Measures"); China's Marketed Drug Patent Information Registration Platform, https://zldj.cde.org.cn/home.

[11] *Id.*

[12] Interim Implementation Measures.

[13] SUPREME PEOPLE'S COURT OF CHINA, Guidelines from the Supreme People's Court on Several Issues Regarding the Application of Law in Adjudicating Civil Patent Cases Relating to Drug Registration" (July 5, 2021) ("SPC Judicial Guidelines"); CNIPA, Measures for Administrative Adjudication Concerning Early Resolution of Drug Patent Disputes (July 5, 2021) ("CNIPA Administrative Adjudication Guidelines").

[14] *See, e.g.*, China's Proposal to Provide a Patent Linkage System and Patent Term Extensions – Considerations for Drug Companies (July 27, 2020), https://www.paulhastings.com/insights/client-alerts/chinas-proposals-to-provide-a-patent-linkage-system-and-patent-term-extensions-considerations-for-drug-companies; Takeaways from China's Proposed Regulation to Implement a Drug Patent Linkage System (Oct. 5, 2020), https://www.paulhastings.com/insights/client-alerts/takeaways-from-chinas-proposed-regulation-to-implement-a-drug-patent-linkage-system.

[15] In addition to small molecule and biologic drugs, China's patent linkage system also cover traditional Chinese medicine.

[16] Interim Implementation Measures, at Arts. 7, 12.

[17] *Id.*

[18] China's Patent Law, at Arts. 45-46.

[19] Interim Implementation Measures, at Arts. 6, 12.

[20] *Id.*; China's Marketed Drug Patent Information Registration Platform, https://zldj.cde.org.cn/home.

[21] Interim Implementation Measures, at Arts. 6, 12.

[22] *Id.* at Art. 8.

[23] SPC Judicial Guidelines, at Art. 10.

[24] Interim Implementation Measures, at Art. 11.

[25] *Id.*

[26] SPC Judicial Guidelines, at Art. 12.

[27] Interim Implementation Measures, at Arts. 4, 5.

[28] *Id.* at Arts. 4, 12.

[29] NMPA AND CNIPA, Policy Interpretation Regarding the Implementation Measures for a Mechanism for Early Resolution of Drug Patent Disputes (Trial), § 4 (July 4, 2021).

[30] 21 C.F.R. § 314.53.

[31] 42 U.S.C. § 262(k)(9)(A).

[32] Interim Implementation Measures, at Art. 3.

[33] U.S. Food and Drug Administration, Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations, https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[34] 42 U.S.C. § 262(k)(9)(A); Purple Book: Database of Licensed Biological Products, https://purplebooksearch.fda.gov/.

[35] Interim Implementation Measures, at Arts. 6, 12; China's Marketed Drug Patent Information Registration Platform, https://zldj.cde.org.cn/home.

[36] 21 U.S.C. § 355(j)(2)(A)(vii).

[37] 42 U.S.C. § 262(l).

[38] Interim Implementation Measures, at Arts. 6, 12.

[39] *Id*.

[40] *Id*.; China's Marketed Drug Patent Information Registration Platform, https://zldj.cde.org.cn/home.

[41] 21 U.S.C. § 355(j)(2)(B)(iv)(II).

[42] 21 U.S.C. § 355(j)(5)(C)(i)(III).

[43] 42 U.S.C. § 262(l).

[44] Interim Implementation Measures, at Arts. 7, 12.

[45] 35 U.S.C. § 271(e)(2).

[46] Interim Implementation Measures, at Arts. 7, 12.

[47] 21 U.S.C. § 355(j)(5)(B)(iii).

[48] 42 U.S.C. § 262(l).

[49] Interim Implementation Measures, at Arts. 7, 12; SPC Judicial Guidelines, at Art. 1; CNIPA Administrative Adjudication Measures.

[50] 28 U.S.C. §§ 1331, 1338(a), 2201, 2202; 35 U.S.C. § 271.

[51] Interim Implementation Measures, at Art. 8; SPC Judicial Guidelines, at Art. 4.

[52] 21 U.S.C. § 355(j)(5)(C)(i)(I).

[53] Interim Implementation Measures, at Art. 8.

[54] *Id*. at Art. 13.

[55] 21 U.S.C. § 355(j)(5)(B)(iii).

[56] 42 U.S.C. § 262(l)(8).

[57] SPC Judicial Guidelines, at Art. 11.

[58] *E.g., Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009).

[59] Interim Implementation Measures, at Art. 11.

[60] *Id.*

[61] 21 U.S.C. § 355(j)(5)(B)(iv).

[62] SPC Judicial Guidelines, at Art. 12.

[63] 35 U.S.C. § 285.

[64] CNIPA, Comparison Table Regarding Amendments to Patent Examination Guidelines (Draft for Comments) ("Draft amendments to China's patent examination guidelines") (Aug. 3, 2021), at Part 4, ¶ 3, Art. 8.

[65] *Id*. at Part 4, ¶ 3, Art. 8.1.

[66] CNIPA, Notification on Seeking Public Comments to Amendments to Patent Examination Guidelines (Draft for Comments) (Aug. 3, 2021), https://www.cnipa.gov.cn/art/2021/8/3/art_75_166474.html.

[67] Draft Amendments to China's patent examination guidelines, at Part 4, ¶ 3, Art. 8.2.

[68] *Id*. at Part 4, ¶ 3, Art. 8.3.

[69] *Id*.

[70] *Id*. at Part 4, ¶ 3, Art. 8.4.

[71] *Id*.