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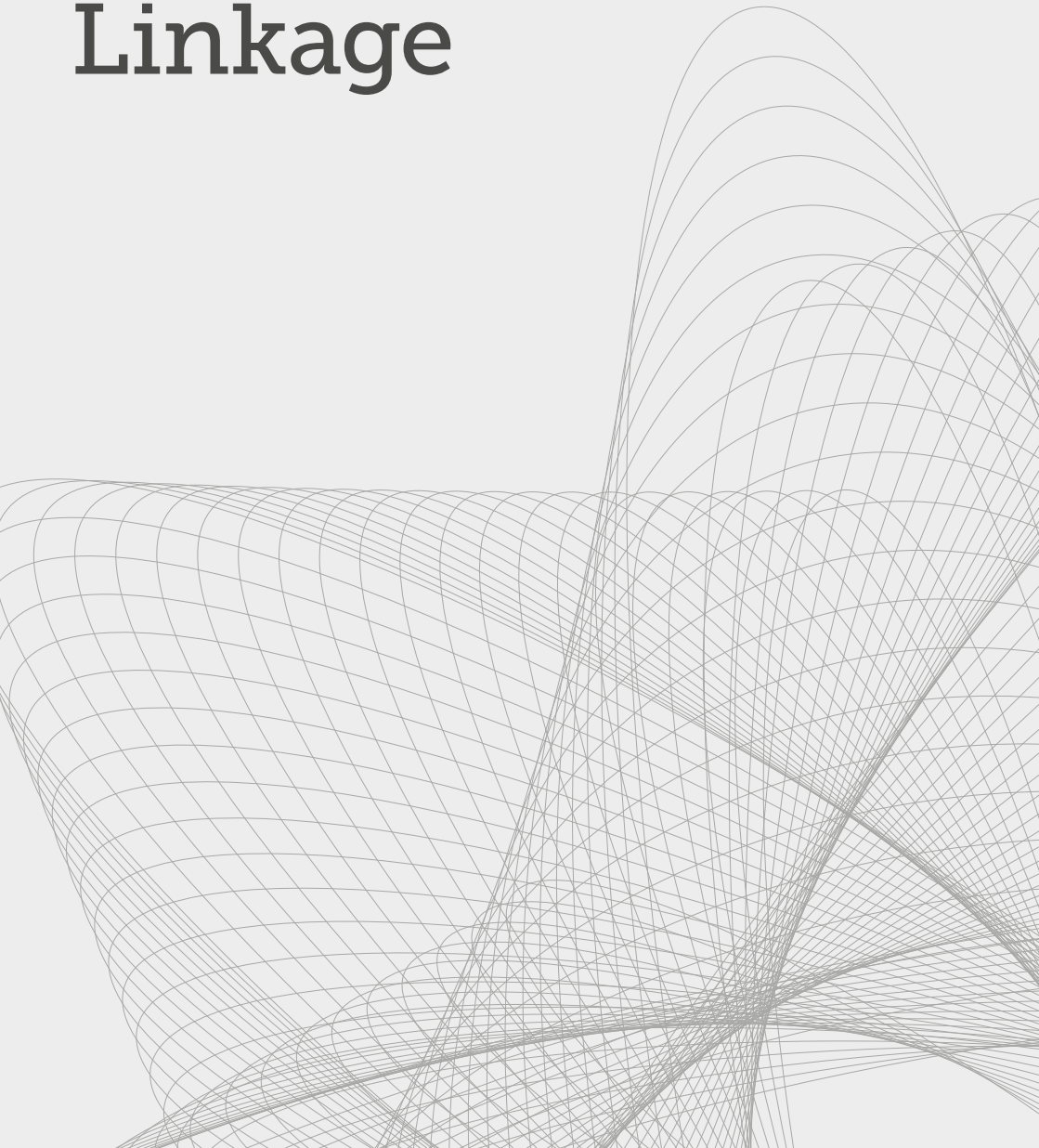
Patent Linkage

Global summary created by:
Phil Docherty and Philip French



The topic of this global summary is patent linkage, which is a powerful tool for a patentee to protect their pharmaceutical products in certain jurisdictions. This document is of relevance to pharmaceutical innovators, legal professionals, and manufacturers of generic pharmaceuticals.

What is it?

Patent linkage refers to a system whereby marketing approval for a therapeutic product is linked to the patent(s) associated with the original innovator's product. It is particularly pertinent for the approval of generic drugs, which can be refused marketing approval until the original patents have expired. In practice, patent linkage can involve the drug authority checking a patent database to assess whether a generic product infringes a patent right of an innovator's drug before the authority determines the generic drug's marketing approval.

Is it widely used?

There has not been an uptake in patent linkage worldwide. Detractors contend that it can delay the market entry of generic medicines and therefore increase the cost of medication. Proponents of patent linkage argue that it can help innovators to prevent anticipated patent infringement, thereby promoting innovation and investment. Only time will tell whether patent linkage becomes the global standard for pharmaceutical intellectual property.

Where is it in use?

To date, 15 World Trade Organization (WTO) member states have directly implemented recognisable patent linkage systems, the best known being the US 'Orange Book'. These are:

Australia, Canada, China, Japan, Jordan, Mexico, Morocco, Peru, Saudi Arabia, Singapore, South Korea, Taiwan, Ukraine, the United Arab Emirates, and the United States of America.

This is the list at the time of writing in 2023, but the number of states implementing some form of patent linkage is likely to increase as the ratification of regional trade agreements that include patent linkage provisions takes place.

An added complication for defining which states have a patent linkage system is the variety of different forms of patent linkage that the states have enacted. Some states do not formally refer to their system as 'patent linkage' or 'linkage' despite being similar in everything but name. The opposite can also be true, where states do have a formal patent linkage system but its powers are so dilute that the system is unrecognisable.

The European Union (EU) does not support a patent linkage system as it might undermine a patent exemption provision that is devised to encourage rapid access of generic drugs to the EU market post patent expiry. This provision allows a drug manufacturer to work with any patented drug during the patent term to generate data that could be submitted to the regulatory authorities for marketing approval. The existence of a patent is not grounds for refusal, suspension, or revocation of marketing approval. The same goes for the United Kingdom, which has so far aligned itself with the EU approach.

Some countries have chosen to forego their patent linkage system. One notable example is the Philippines, which removed its patent linkage system in 2006 following a Government Administrative Order. This may change in the near future, however, as the general momentum in Southeast Asia is towards more patent linkage provisions as they align with their North American counterparts.

United States of America

The concept of patent linkage was first established in the United States of America (USA) through the Drug Price Competition and Patent Term Restoration Act of 1984, better known as the Hatch-Waxman Act. To regulate this process, the Food and Drug Administration (FDA) uses the *'Orange Book'*, which lists approved drugs along with their patent and exclusivity information. Before approval of an Abbreviated New Drug Application (ANDA), the generic drug manufacturer must certify one of the following four criteria:

I. The drug has not been patented.

II. The patent has already expired.

III. The generic drug will not go on the market until the expiry of the patent.

IV. The patent is not infringed or is invalid.

For criteria I and II, the FDA may grant approval immediately provided that the applicant has demonstrated the drug's bioequivalence to the original patented drug. Similarly, for criterion III the FDA may grant ANDA approval on the expiry of the patent term.

For criterion IV, the applicant for marketing approval must notify the patentee of its filing and provide their reasoning why the proposed generic drug does not infringe and/or why the patent is invalid. The patentee then has 45 days after notice to file an infringement suit (often referred to as a paragraph IV suit). If an infringement suit is filed, an automatic 30 month delay-of-marketing approval is placed on the generic drug. If patent expiration occurs, or the court determines the patent invalid or not infringed, within the 30 month period, or if the 30 month period expires, the FDA can grant immediate approval for the ANDA. If the patent is determined to be valid and infringed then the generic drug will not be approved until the expiration of the patent term. As an incentive to generic companies to use the Hatch-Waxman system, the first applicant of a generic drug to successfully challenge a patent's validity, or show that it will not be infringed, is granted 180 days of generic market exclusivity. This is of significant value to a generic company as it provides a period during which they are the only generic on the market.

A separate linkage system in the USA exists for patented biologics but this system does not include a patent list – that is to say there is no *'Orange Book'* equivalent for patented biologics.

Summary of other patent linkage systems

States which implement patent linkage may mirror the model used by the USA, sometimes to facilitate a free trade agreement (FTA). However, even in these cases, there are differences.

State	Patent list	Patent litigation	Generic Exclusivity[1]
USA	Yes	45 days to file infringement action; 30 month stay-of-approval.	180 day exclusivity.
Australia	No	*Notification only.*	-
Canada	Yes	45 days to file infringement action; 24 month stay-of-approval.	-
China	Yes	45 days to file infringement action; 9 month stay-of-approval	12 month exclusivity.[2]
Japan	Yes	*Notification only.*	-
Jordan	No	*Notification only.*	-
Mexico	Yes	*Notification only.*	-
Morocco	No	*Notification only.*	-
Peru	No	Marketing approval deferred until patent expiry or dispute cessation.	-
Saudi Arabia	No	Notification only.	-
Singapore	No	45 days to file infringement action; 30 month stay-of-approval.	-
South Korea	Yes	45 days to file infringement action; 9 month stay-of-sales.	9 month exclusivity.
Taiwan	Yes	45 days to file infringement action; 12 month stay-of-approval.	12 month exclusivity.
Ukraine	No	*Notification only.*	-
UAE	No	*Notification only.*	-

1 Generic exclusivity indicates the amount of time a generic drug manufacturer is afforded market exclusivity after being the first to successfully challenge a patent's validity or show that it will not be infringed.

2 In China, a generic drug manufacturer can be afforded market exclusivity only after successfully challenging a patent's validity. A judgment or ruling showing non-infringement cannot win market exclusivity.

Australia

Australia introduced a diluted form of patent linkage in 2005 as part of the implementation of their FTA with the USA. Unlike the USA, there is no administrative patent linkage in Australia. A generic manufacturer need only certify that it will not market the drug in a manner that would infringe a valid patent or that it has notified the patentee of their intention to market the drug before the expiry of the patent term. After an applicant's notice of intention to market a generic drug before the patent term expiry, the patentee must seek an injunction against sale if they what to restrain the generic manufacturer's activities. There is no process to prevent the grant of marketing approval. This passive process means the drug regulator does not adjudicate the process and is required only to ensure that the notification by the generic manufacturer has been received. Australia's patent linkage system is the same for biologics.

Canada

Canada introduced a form of patent linkage in 1993 as part of the implementation of their FTA with the USA and their patent linkage system mirrors the USA system closely. Following notification, the patentee has 45 days to file an infringement suit. If an infringement suit is filed, an automatic 24 month stay-of-approval is given to the generic manufacturer. Notably, no marketing exclusivity is afforded to the first generic drug manufacturer to challenge a patent's validity, or show that the patent will not be infringed. Canada's patent linkage system is the same for biologics.

China

In 2020, Article 76 was added to China's patent law to establish a patent linkage system. In this recent development, the drug marketing authorisation holder is required to register their new therapeutics with the drug regulatory department within 30 days of receiving their drug registration certificate. After a generic drug application is accepted with a statement as to the patent status, the national drug review agency discloses the application information and the corresponding statement to the public within 10 working days. The generic drug applicant is responsible for notifying the marketing authorisation holder of the statement and the basis for the statement. In cases where the marketing authorisation holder is not the patentee, the marketing authorisation holder shall notify the patentee. Following notification, the patentee has 45 days to file an infringement suit in the People's Court or request an administrative ruling from the China National Intellectual Property Administration. If an infringement suit is filed or if there is a request for administrative ruling, the department puts in place a 9 month stay-of-approval for the generic drug. The first generic drug applicant to successfully challenge the patent and be approved for marketing is afforded 12 months of generic market exclusivity, or until the expiration of the term of the original patent(s), whichever is sooner. A judgement or ruling indicating non-infringement cannot be afforded generic market exclusivity. China also has a patent linkage system for biologics, however, there is no stay-of-approval mechanism in these cases.

Japan

Japan's patent linkage system has been in operation since 2009 and is perhaps more complex than their US counterpart's. It is generally understood that the patent linkage system in Japan operates under the administration of the Ministry of Health, Labour, and Welfare (MHLW) and includes two stages: pharmaceutical approval and National Health Insurance (NHI) drug price listing. The latter stage results in drug prices that are determined by the state, which reduces competition between originator drugs and generic drugs in the first instance. This is a system unique to Japan that is not clearly stipulated by law.

Firstly, an innovator may submit their patent information on a marketed product to the MHLW. Submission is not mandatory, and the contents are not disclosed to the public. Upon submission for marketing approval by a generic manufacturer, the MHLW checks the patent status but it does not examine whether the patent will be infringed. This is followed by discussions between the patentee and the generic manufacturer in the two stages mentioned above. The MHLW offers the opportunity for the discussions to take place but it does not take a position or intervene in further patent litigation between the parties. Discussion between the parties may result in the generic company withdrawing its application or the innovator filing legal proceedings against the generic company. In principle, this means that no marketing approval is granted to the generic manufacturer before the patent is invalidated. However, there are exceptional cases where generic manufacturers were afforded marketing approval before invalidation of the patent. As long as the application is not withdrawn by the generic company, the MHLW will proceed with the examination for marketing approval. Only small molecule medical products are subject to the patent linkage procedure, meaning the notification provision is not relevant to biologics.

In summary, there is a formal patent linkage procedure in Japan but its influence is diluted.

Jordan

Jordan has maintained a patent linkage system since its FTA with the USA in 2001. This patent linkage system is less far-reaching than its US counterpart's. Upon a generic company requesting marketing approval, the Jordan Food and Drug Administration (JFDA) notifies the patentee, according to Article 4.23.b of the Jordan-United States FTA. Following notification, the responsibility for litigation lies with the originator drug company and there is no stay-of-approval of the generic drug.

Mexico

Unlike other patent linkage systems, patent linkage in Mexico is predominantly managed by the market regulator and the patent office with limited participation from the relevant parties. The patent linkage system in Mexico is established under Article 167bis of the Health Supplies Regulation and Article 162 of the Industrial Property Law act of 2020. A gazette listing of patents, and the non-proprietary names (INN) of compounds covered by them, was established by the Mexican Institute of Industrial Property (IMPI). On receiving a request from a generic manufacturer for marketing approval, the Federal Commission for Protection Against Health Risks (COFEPRIS) first reviews the gazette to determine if relevant patents are listed and, in case of any doubt, COFEPRIS sends a request to the IMPI to establish if a patent will be infringed. If the IMPI suspects there are grounds for infringement then they will notify COFEPRIS which will, in turn, notify the applicant of the possible infringement. If the generic applicant is unable to technically demonstrate that the product for which registration is sought is out of the scope of the patents listed in the gazette, or the ones detected in IMPI's report, the marketing authorisation is denied until the end of the patent term or until the patent is successfully annulled. In practice, because the IMPI are required to perform a full freedom to operate search in 10 days, they are unable to provide a definitive opinion or conclusion. Therefore, the burden of proof remains with the innovator, who submit their arguments to COFEPRIS to make a final decision without consulting IMPI.

Morocco

Morocco signed a FTA with the USA in 2006, which includes a patent linkage system as per Article 15.10.4. of the FTA. Upon submission of a marketing approval request by a generic drug manufacturer, the drug regulatory authority will notify the patentee. Following infringement proceedings, if the generic drug is deemed by the courts to infringe the originator's patent, the marketing approval of the generic drug will not be granted until the expiration of the patent term or until the patent is successfully opposed.

Peru

Article 16.10.4 of the US-Peru FTA of 2009 provides patent linkage provisions. The patent holder is informed of the application for marketing approval by a generic company. Following infringement proceedings, if the generic drug is deemed by the courts to infringe the originator's patent, then marketing approval is deferred until the patent has expired or until the dispute on the status of the patent has concluded. Item (d) of Article 16.10.4 provides "effective rewards for a successful challenge of the validity or applicability of the patent" for a generic manufacturer. A period of marketing exclusivity is suggested in a footnote of the US-Peru FTA as a suitable reward for the first generic manufacturer to challenge the validity or applicability of a patent. However, little information exists about how long the market exclusivity is in place for and there are no obvious cases where market exclusivity has been offered to a generic manufacturer. As Peru is a signatory to the CPTPP, there may be further modifications to Peru's patent linkage system in the future.

Saudi Arabia

Patent linkage was implemented by the Saudi Food and Drug Authority (SFDA) in 2023 under Circular Letter No. 7448. Originator pharmaceutical and biotech companies should disclose any relevant Saudi and/or Gulf Cooperation Council (GCC) patents when applying for marketing authorisation from the SFDA. A generic drug can only be registered and marketed if a drug's corresponding patent has expired or if the SFDA determines that the patent is not valid or not infringed by the generic drug. Therefore, the SFDA is responsible for both regulating the pharmaceutical market in the country and enforcing the patent linkage system.

Singapore

Singapore implemented a patent linkage system in 2004 after entering a FTA with the USA. There is no patent listing in Singapore. Instead, generic drug manufacturers are required to declare whether a patent is in force "in respect of the therapeutic product". After notification by the generic drug manufacturer that they are seeking marketing approval, the patentee has 45 days to file a complaint with the Central Competent Health Authority, who may then refuse to register the generic therapeutic product for a period of 30 months. After 30 months, the Health Authority may register the product without further notice if no further order or declaration has been made by the patentee.

South Korea

South Korea introduced a form of patent linkage in 2015 as part of the implementation of their FTA with the USA. Following notification of a generic application for approval, the patentee has 45 days to file an infringement suit. If an infringement suit is filed an automatic 9 month stay-of-sales is imposed on the generic manufacturer. A generic may receive generic marketing exclusivity for 9 months in South Korea if they are the first to successfully oppose the originator drug's patent or show that it will not be infringed. South Korea's patent linkage system is the same for biologics.

Taiwan

Patent linkage was introduced to Taiwan through the revision of the Pharmaceutical Affairs Act, Article 48, which was implemented in 2019. The implemented patent linkage system is similar to the USA model, with patentees able to submit their patent information to the Central Competent Health Authority within 45 days from the receipt of the drug permit. Upon notification of a generic application for approval, the patentee has 45 days to file a complaint with the Central Competent Health Authority, who shall stay the issuance of the generic drug approval for 12 months. If the generic drug applicant succeeds in invalidating the patent or showing that it will not be infringed, they are afforded a 12 month period of generic market exclusivity.

Ukraine

Ukraine introduced patent linkage in 1996 by Article 9 of the Ukrainian Law on Medicines and Drugs. This statute states that the application for marketing approval of a generic drug before the expiration of the original drug patent can be considered a violation of the patentee's right. The Protection of Rights to Inventions clarifies that the manufacturing and selling of generic drugs before patent expiration may be considered patent infringement. However, the patentee is responsible for monitoring market approvals and subsequently filing patent infringement suits against generic drug applicants. The patentee must take a proactive position and defend their rights in court. Court practice on this issue is almost always in favour of the patentee. In summary, even though Ukraine formally has a patent linkage system in place, it is incumbent on the patentee to defend their rights in court to cancel an issued marketing approval for a generic drug.

United Arab Emirates

The concept of patent linkage was first introduced in the United Arab Emirates (UAE) in the year 2000 by Ministerial Resolution No 404. This was ratified further in Federal Law No. 8 of 2019, which describes how a generic pharmaceutical product may receive marketing authorisation based on its bioequivalence and qualitative equivalence to another product, for which the legal protection has ended and has previously obtained marketing authorisation. The patentee is notified if a generic manufacturer applies for marketing approval. If the generic drug is deemed by the UAE Ministry of Health & Prevention (MOHAP) to infringe the patent, marketing approval is deferred until the patent has expired or until the dispute on the status of the patent has concluded.

Regional trade agreements and partnerships

Regional trade agreements and partnerships are one of the main drivers for patent linkage implementation. The Regional Comprehensive Economic Partnership (RCEP) and the CPTPP are two examples which will require signatories to implement patent linkages at some point. Countries that are party to these agreements, and are not mentioned above, are likely to introduce some form of patent linkage in the near to medium term future.

Conclusion

Patent linkage is a powerful tool that confers additional protection to a patented pharmaceutical. The exact protocol of the patent linkage provision depends on the jurisdiction. The first and perhaps the most notable form of patent linkage is applied by the USA, who offer a 30 month delay-of-marketing approval of a generic pharmaceutical to the patentee. Some countries adopt the USA's system closely whilst other countries have more modest rights for the patentee.

This summary is guidance material only and should not be considered legal advice. Instead, it serves to educate the reader about patent linkage systems worldwide. We recommend consulting your Abel + Imray contact for the most up-to-date information about your market of interest.

Whilst every effort has been made to ensure this summary is accurate, on occasion, secondary sources of information have been used. Furthermore, laws and regulations concerning patent linkage are subject to change. For at least these reasons, this document should not solely be relied upon to inform readers on legal or commercial matters.

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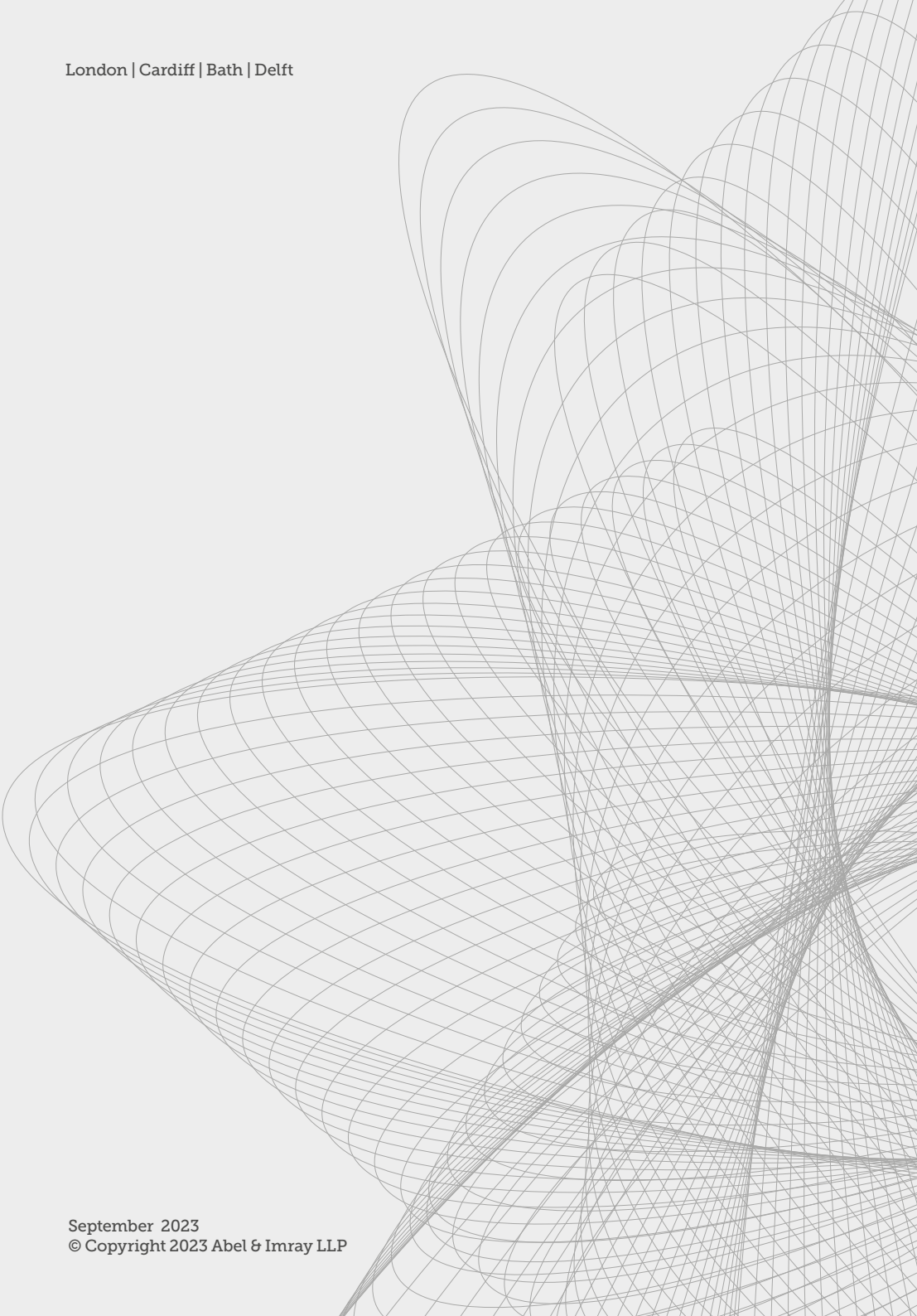

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