

# *Data Exclusivity in South Korea: Strategies for Brands & Generics*

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# Data Exclusivity - Changes & Related Issues

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- As of May 5, 2021, **pediatric drugs** for which clinical trials were conducted **outside** the territory of Korea became subject to re-examination for post-marketing surveillance (PMS).
  - Prior to the amendment, only pediatric drugs approved based on “domestic” clinical trials were subject to re-examination.
  - In Korea, the re-examination period under PMS acts as *de facto* **Data Exclusivity (DE)**. During this period, follow-on generic companies cannot obtain marketing approval (MA) unless they submit their own safety and efficacy data.
- There are some notable features in the Data Exclusivity system of Korea, especially in relation to
  - Patent infringement, Clinical trial, and **Research exemption**
  - Patent Term Extension and **Drug Patent Linkage System**
  - Application to **Biologics**
- By understanding these interacting systems, brand or generic companies may optimize their strategies in the market. Please see **our comments** in this regard.

# De Facto Data Exclusivity of Korea

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- In Korea, marketing-approved drugs falling under certain criteria are subject to re-examination for a certain period of PMS.
- **During** the re-examination period, a follow-on generic company seeking MA for the same product must **submit safety and efficacy data** equivalent to or exceeding the scope of the original MA holder's data,  
*except* in the following cases:
  - when permission (to use the data) has been obtained from the original MA holder; or
  - when an application is filed on the condition that the MA will be granted after expiration of the re-examination period.
- **After** the re-examination period expires, the generic company can obtain MA by submitting **biological equivalency data**, instead of full safety and efficacy data.
- Since the generic companies cannot rely on the original MA holder's data during the re-examination period, PMS acts much like data exclusivity in other jurisdictions.

# Re-examination Period

- The following table summarizes eligible drugs and the re-examination periods.

	Criteria	Period
1-i	<b>New drugs</b> – drugs of which the chemical structure or essential component is novel and different from those of already-authorized drugs	6 years
1-ii	<b>New combination</b> – prescription drugs different from already-authorized drugs in terms of active ingredient(s) or combination ratio	
1-iii	<b>New administration route</b> – prescription drugs different from already-authorized drugs in terms of administration route, while containing the same active ingredient(s)	
2-i.	<b>New indication</b> – prescription drugs identical to already-authorized drugs in terms of active ingredient(s) and administration route(s), but having clearly different indication(s) added	4 years
2-ii	<b>Other drugs</b> – determined by the MFDS	
3-i	<b>Orphan drugs</b> for use in a disease for which adequate treatment and medicines have not been developed <ul style="list-style-type: none"> <li>upon the applicant's request for re-examination</li> </ul>	10 years
3-ii	Orphan drugs of 3-i where a pediatric indication is added	11 years

# Re-examination Period

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- Regarding **Criterion 2-ii** (Other drugs determined by the MFDS), the following cases are included:
  - **Pediatric drugs** – drugs which have been approved for pediatric dose and dosage regimen through clinical trials
  - **Orphan drugs**
    - Accordingly, for pediatric or orphan drugs, 4-year data exclusivity is available even if they do not meet Criteria 1-i to 1-iii, 3-I, and 3-ii.
- For orphan drugs under **Criterion 3-i** (Orphan drugs for use in a disease for which adequate treatment and medicines have not been developed), 10-year re-examination can be granted upon the applicant's request.
- Further, for orphan drugs under **Criterion 3-ii** (Orphan drug of **3-i** where a pediatric indication is added), the period of re-examination can be extended by 1 year, *i.e.*, for 11 years in total.

# Exemption from Re-examination

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- MFDS may exempt the re-examination of the drugs for any of the following, at its discretion:
  - Pesticides, *etc.* which are not directly applied to a human body
  - Orphan drugs
  - Drugs for which re-examination is considered unnecessary due to lack of novelty
  - Drugs whose safety and efficacy are considered to be sufficiently ensured
  - Drugs for which the number of patients to be surveyed is too small to meet the re-examination requirements
- As a natural consequence, data exclusivity will **not** be provided if re-examination is exempted in the above cases.

# Generic Company's Applying for MA during DE Period

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- A generic company can *theoretically* **apply for and obtain** MA during the Data Exclusivity period.
  - Unlike some other jurisdictions where exclusivity operates by prohibiting the submission or approval of drug applications, there is no such bar in Korea.
  - Therefore, a generic company can theoretically apply for and obtain MA even during the re-examination period if the company provides its own safety and efficacy data.
    - e.g., Ahngook Pharm applied for and obtained approval for *Anyfen* (dexibuprofen syrup) during the 4-year re-examination period of Hanmi's *Maxibufen* by providing its own clinical trial data.

# Generic Company's Applying for MA under Patent

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- Applying for marketing approval is **not** patent **infringement**.
  - Korean Patent Act stipulates that a practicing of patented inventions constitutes patent infringement. [KPA, Art. 94]
  - Practicing of a “product” invention is defined as an act of one of: (i) manufacturing, (ii) using, (iii) assigning, (iv) leasing, (v) importing, and (vi) offering (or displaying) to assign or lease the product.
  - An act of applying for MA does not constitute patent infringement because it does not fall under any of (i) to (vi) above.
  - However, it should be noted that **if** the patent is **listed** under the Drug Patent Linkage System, such act of applying for MA must be accompanied by a **Generic Notice** which includes grounds for invalidity or non-infringement of the listed patent, *unless* the application is filed on the condition that the product will be sold after the expiration of the patent.

# Research Exemption in Korea

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- The Korean Patent Act has a provision for **research exemption**; that is, practicing a patented invention for the purpose of research or experimentation is exempted from infringement.
  - KPA Art. 96 stipulates that the “research or experimentation” *includes* “research or experimentation for obtaining MA of a drug under the Pharmaceutical Affairs Act”.
- As such, using the patented drug for the purpose of preparing safety and efficacy or biological equivalency data in order to apply for MA is statutorily exempted from patent infringement.
  - Generic companies may conduct research, **clinical trials, or biological equivalency tests** even there is a patent covering the product.

# Interplay with Patent Term Extension

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- **Patent Term Extension (PTE)**

- If there is a first marketing approval of a new substance, patents related thereto may be eligible for PTE as well as data exclusivity.
- The term of a patent can be extended for up to 5 years, corresponding to the period that the patented inventions could not have been practiced. This extendible period is usually the sum of the clinical trial and regulatory review periods.
- Under the current law, MA obtained for a second indication of a known substance is not eligible for PTE.
- In order to obtain PTE, the MA holder must be a patentee or a registered (exclusive or non-exclusive) licensee.
- Unlike in Europe, a **pediatric** indication does **not** lead to additional extension of the patent term.

# Patent Linkage System in Korea

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## ● Drug Approval–Patent Linkage System

- Korea has a patent linkage system which is similar to the “Hatch–Waxman system” in the U.S.
- A marketing approval holder can file a request for a patent listing with the Korean MFDS (**Patent Listing**).
- Any third-party generic company seeking marketing approval based on the safety and efficacy data of the listed drug must *notify* the patentee/approval holder of **(i)** the fact that the application for such marketing approval was filed and **(ii)** the grounds for invalidity or non-infringement of the listed patent (**Generic Notice**).
- The patentee may request a *stay* of generic sales in order to delay the entry of generic products into the market for 9 months, provided that the patentee filed a legal action\* or the generic company filed a trial\*\* against the patent (**Stay of Generic Sales**).

\* patent infringement litigation or a trial to confirm the scope of a patent right

\*\* a trial to confirm the scope of a patent right

# Patent Linkage System – First Generic Exclusivity

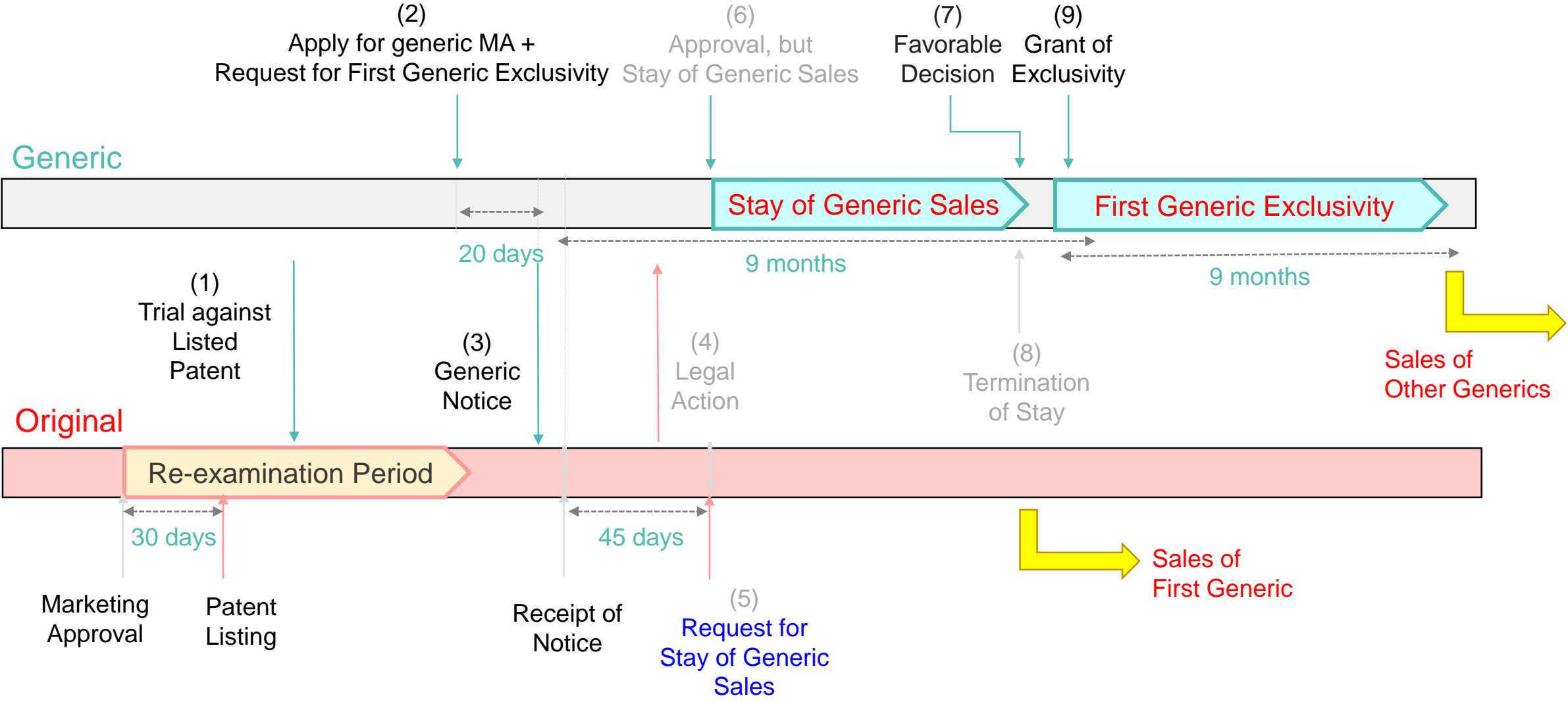
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- **First Generic Exclusivity**

- A generic company may challenge a listed patent to obtain so-called First Generic Exclusivity of 9 months.
- In order to obtain the First Generic Exclusivity, the generic company must satisfy *all* of the following requirements:
  - **The First MA Applicant** – A generic company who filed the MA earliest (includes all applicants on the same day);
  - **Successful Patent Challenge** – A generic company who received a favorable decision in a trial\*\*\* against the patent within 9 months of the date of receipt of the Generic Notice; and
  - **First-Trial Prerequisite** – A generic company who (i) first filed a trial, or (ii) filed a trial within 14 days after the filing of the trial (i), or (iii) a generic company who “received” a favorable decision earlier than the company of (i) or (ii).

\*\*\* a patent invalidation trial, or a trial to confirm the scope of a patent right

# Patent Linkage System – Illustration



# First Generic Exclusivity, DE, and Patent Invalidation

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- **First Generic Exclusivity**

- The First Generic Exclusivity is granted to the generic company *only when* it applies for the MA based on the safety and efficacy data of the listed drug, *i.e.*, after the expiration of the DE period of the listed drug.
- In addition, First Generic Exclusivity can be requested *only if* the patent is validly listed at the time the generic company applies for MA.
- To satisfy the First-Trial Prerequisite requirement, it would generally be advantageous for generic companies to file the invalidation trial as early as possible.
- However, generic companies would forfeit their opportunity to become a First Generic if the patent is invalidated too early, and as a consequence, it is not validly listed when the company applies for MA.

# Biologics

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- **Data Exclusivity**

- Biological drugs are also subject to re-examination, and thus may enjoy similar *de facto* data exclusivity like chemical drugs.
- However, even if the data exclusivity period expires, a generic company seeking MA for a biosimilar product must submit *comparability data* with a reference product which includes Phase I and III clinical trial data.
- Therefore, a generic company still bears a burden for providing clinical trial data to obtain MA of a biosimilar even after the data exclusivity period.

- **Patent Term Extension**

- Biological drugs may obtain patent term extension based on its MA.

# Our Comments for Brand Companies

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- While a patent can provide strong protection for drug products, it has some drawbacks in that it can be “**invalidated**” during the term.
  - In most cases (assuming the patent survives the challenge), the period of DE will end before the term of the patent, and thus, DE may not function as a main shield to the competitors.
  - However, when the **inventiveness** of a patent is relatively **weak**, the DE may become the only practical defense against competitors.
    - For reference, the average rate of patent invalidation in Korea is about 47% (2021, statistics up to June)
- Data Exclusivity may play a more important role in some types of drugs, for example, so-called “**incrementally modified drugs**”.
  - Incrementally modified drugs are those having some improvements to existing drugs, such as new combination and new administration routes (Criteria 1-ii and 1-iii). These are entitled to a 6-year DE period, which is relatively long compared to other jurisdictions.
  - Incrementally modified drugs may be allowed to obtain **MA and DE**, but may **not** be protected as **patents** because their technical improvement is not very remarkable. In which case, understanding the DE system will be crucial in strategic planning of the drug marketing.

# Our Comments for Follow-on Generics

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- Generic companies frequently challenge the patents of original drugs. Those wishing to be the **First Generic** need to further **tune** the time of patent invalidation.
  - Those companies who filed an invalidation trial first or received a favorable decision first may become the first generic that has the First Generic Exclusivity.
    - To satisfy the First-Trial Prerequisite, it is generally advantageous to initiate the invalidation proceedings as early as possible.
  - In order to request First Generic Exclusivity, the generic company must apply for MA after expiration of the DE. In addition, First Generic Exclusivity can be requested **only if** the patent is validly listed at the time the generic company applies for MA.
    - Since the invalidated patent will be deleted from the list, if the patent is invalidated too early, the opportunity to become the first generic may also disappear.
    - As such, those seeking to obtain the First Generic Exclusivity need to ensure that the patent is not invalidated too early before they can apply for the MA.

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