Issue of Data Exclusivity

Why in news?

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- April 26 is World Intellectual Property (IP) day.
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- The recent debate whether India would offer data exclusivity - one of the key issues discussed in the RCEP.
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What is the issue?

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- Global IP standards have steadily expanded beyond World Trade Organisation (WTO) requirements, thanks to free trade agreements such as the RCEP which India is currently negotiating.
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- But apart from increasing the scope of existing IP rights, **there is a move to create new IP-like rights.**
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- A case in point is data exclusivity over clinical trial data submitted by drug companies to the regulatory authorities for market approval, the grant of which could severely undermine access to medicines.
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What is the issue with data exclusivity?

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- Data exclusivity **prevents drug regulators** from referring to or relying on data submitted by an originator company relating to a drug's safety and efficacy while approving bioequivalent versions of the same drug, i.e. therapeutically equivalent generics and bio-similars for a fixed period of time.

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- A drug that comes to the market for the first time undergoes extensive preclinical and clinical trials on animals initially and human being later before it is introduced for public use which is a time-consuming and expensive process.
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- Developed countries, on behalf of their pharmaceutical lobbies, seek data exclusivity in developing countries.
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- They arguing that this is necessary to recognise and incentivise the efforts put in to bring a new drug to the market along with recovering the R&D costs incurred — arguments similar to those used to justify the grant of patents.
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- However, such **exclusivity would prevent market entry of generic versions of the drug,** which could be detrimental to the larger public interest.
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- Pharmaceutical companies have been pushing for data exclusivity to prolong already existing monopoly and delay competition from generics even after the expiry of the 20-year patent term or to gain exclusivity on non-patented drugs.
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- In India, such a system may negate the impact of **Section 3(d) of the Patents Act,** which **disallows ever-greening patents.**
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- With data exclusivity, a company could nevertheless gain exclusive rights over such drugs even though they are not patented.
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- This is because during the period of exclusivity, regulators are barred from using the originators' data to grant marketing approval to generics.
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- Generic companies would then be required to repeat the entire cycle of clinical trials already conducted instead of merely establishing bioequivalence to prove efficacy.
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- As seen in countries where data exclusivity is granted, generic companies do not undertake such clinical trials and their versions of the drug stay off the market as long as data exclusivity lasts.
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- With restricted market entry of generics, artificially **high drug prices remain which puts medicines beyond public reach.**
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- Apart from the financial costs, repeated clinical trials on human subjects

raise **ethical and moral concerns.**
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- Unlike in the West, **India does not offer data exclusivity** and allows bioequivalent generics to be registered based on, among other things, trial data available in the public domain.
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What is the flaw in the argument put forth by pharma companies?

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- Automotive companies spend millions of dollars on data generated in car crash tests to ensure passenger and pedestrian safety and they have not claimed anything on their data.
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- Unlike automotive companies which use crash test dummies, pharmaceutical companies that test their drugs on human subjects **have a greater obligation** to make the data public and IP-free.
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- The Agreement on Trade-Related Aspects of Intellectual Property Rights **(TRIPS) *does not* mandate data exclusivity.**
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- **Providing data exclusivity is a *TRIPS-plus measure.***
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- It is an absolute protection granted without any institutional check such as opposition and revocation as available in other forms of IP and ends up as an irrevocable exclusivity to the originator.
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- Extending IP-like protection to clinical observations will open a window to claim exclusivity in a subject matter traditionally excluded under patent law.
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- Also, offering IP-like exclusivity solely on the basis of money spent in regulatory testing will set a bad precedent for other industries that may now claim an IP when there is none.
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Source: The Hindu

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