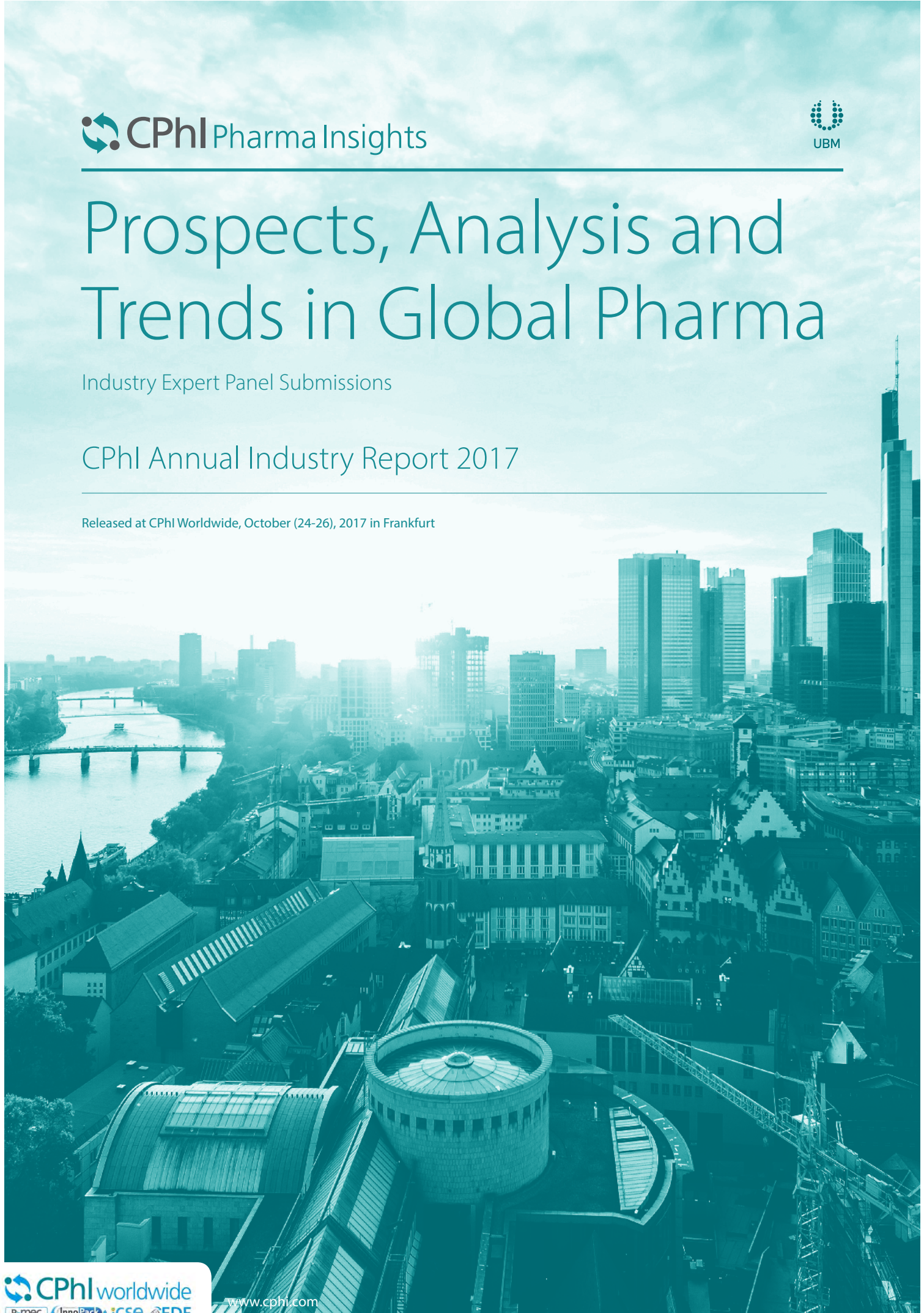


# Prospects, Analysis and Trends in Global Pharma

Industry Expert Panel Submissions

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PANEL MEMBER

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# New Frontiers of Divide: Competition vs Exclusivity

## Introduction

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There is perpetual tension between competition and exclusivity. The competition supports multi-source supply. The exclusivity requires protection for a single source. Both have bearing on access to medicines. The competition ensures access, the exclusivity denies access. This tension got heightened during the negotiations on the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) as developed countries egged by the Big Pharma pushed for higher IPR protection.

The TRIPs Agreement extended the varying terms of patent protection to a uniform period of 20 years, providing legal monopoly to the innovators. What followed is history. The generics invaded the regulated markets, giving rise to many patent litigations. The last two decades witnessed intense conflicts between the Intellectual Property (IP) owners and the generics across the continents. This will continue as the innovators seek to extend their monopoly beyond the 20-year period. However, the onslaught of generics is so intense that the innovator companies are now looking for a shelter beyond IP protection. They are exploring new avenues to keep generics/biosimilars at bay. The innovator companies are frustrated with judiciary's stricter interpretation of patentability norm across the major markets. In addition, many governments burdened with unsustainable health expenditure are having a relook

at the IP laws. Both these have aggravated innovator companies concerns about maintaining exclusivity. Hence, they are looking for ways and means by which they can curb the menace of the generics at source of origin. The battle has therefore moved a few steps backwards. Though, the issues are somewhat different, the confrontation seems to be the re-run of the past. This time round, the issues relate to:

- Innovators blocking access to pharmaceutical reference products for bioequivalence testing, thereby delaying/denying generic entry;
- Innovators using distribution safety protocol, known as Risk Evaluation and Mitigation Strategy (REMS), to impede generic/biosimilar drug development; and
- Innovators challenging the marketing approval granted by the drug regulatory authority to prevent biosimilar products.

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These problems are not new. As the judiciary became more circumspect in its evaluation of alleged patent infringement, the innovator companies are seeking new ways of blocking generics. Till now, they used to block generics after the companies applied for regulatory approval. Now, they seek to block generics at the development stage itself. This gives them multiple opportunities to delay or block the entry of generics. The modus operandi is not only unethical but is abusive. In India, the innovator companies turned to obtaining commercially sensitive information from the office of the drug regulator. They hired a third-party to seek information about generic companies that have applied for import of samples of patented products for development. A law which allows citizens "right to information" on matters of public importance, is thus abused to seek private information.

Thus, equipped with authentic information about the generic companies regarding their development plans, the innovator companies move to the Court. The case is filed to restrain the company from breaching its patent. In reality, the company is only importing samples for development. Another abuse of law. More importantly, the company seeking permission to import is listed as a second or third defendant. The first defendant is an unknown entity – an executive or an independent director of the company. Thus, when the matter is listed, it would not show the name of the company, the real defendant. This ensures that the real defendant is not present in the Court. The matter is heard. The applicant (innovator company) claims that launch of a generic version is eminent. It will cause the right holder "irreparable damage" and gets ex-parte injunction, restraining the company from pursuing all activities related to the development of generic version. Yet one more abuse of law. By the time this unethical and abusive practices came to light, several cases were heard. The innovators succeeded in some, failed in others. They include companies such as Roche, Novartis, Pfizer, etc.

The second and more prevalent practice is not providing samples for bioequivalence. The U.S. Federal Trade Commission (FTC) has intervened in legal disputes between generic and innovator companies for not providing their products for testing. In 2014, FTC backed Mylan's REMS Antitrust Lawsuit against Celgene for bioequivalence testing. There may not be many such

cases, but they could be economically significant. This practice has also attracted attention of the US law makers. The US recently reintroduced a bill: Creating and Restoring Equal Access to Equivalent Samples Act of 2017 (CREATES Act). It speaks for the innovators' abusive practices. Though CREATES Act allows generics to sue innovators for not providing sufficient quantities of REMS products, experts doubt if it would provide optimum solution to the issue. It is possible that under the current regime in the USA, the innovator companies may behave differently to avoid glare of the President. They may also not flout laws to pursue longer period of exclusivity, having regard to the new Administration's focus on raising competition to reduce drug prices in the US.

Among the multiple opportunities that innovator companies now use is one of challenging the decision of the drug regulatory authority. In India, Roche sued Biocon and Mylan to restrain them from selling their biosimilar of breast cancer medicine Trastuzumab. Roche also challenged the drug regulator for approving their biosimilar. It won, but lost in appeal through an interim order. The parties have sued each other for contempt. Subsequently, Biocon and Mylan claimed abuse of dominance by Roche before the competition authority. The competition authority ruled prima facie abuse of dominant position and ordered investigation. Roche has challenged the investigation order raising a fundamental issue: is patent enforcement anti-competitive? While, the matter is still subjudice, it suffices to say that competition authorities have woken up to the abusive anti-competitive practices of innovators. The points to note are innovator companies' recourse to litigations to prevent/delay entry of biogeneric and generic companies' reliance on the competition authority.

The litigations involving competition authority at the development stage have so far been few. Not because abuses do not take place. They occur all the time. But, generic companies are hesitant to take them up for two reasons. Firstly, they do not want their competitors to find out their product development focus and strategy. Secondly, many of them have some form of commercial alliance with the innovator companies. And, they do not wish to adversely impact their commercial alliance. However, once their pipeline of new products is chocked, generic companies will have no option but to invoke both, the competition authority and the drug regulator to have timely access to samples. In

this context, FDA Commissioner, Dr Scott Gottlieb's statement is noteworthy. He told CNBC: "We don't play a role in drug pricing, but we do affect drug competition in terms of getting new drugs on to the market, and create competition to older drugs, particularly with generic drugs". Though, he has limited his ambit to "older drugs" with focus on "generics", it is not too farfetched to expect him to address the issue of competition in biogenerics for products going off-patent in the near future. The same logic will force him to address the issue of lack of competition for new drugs going off-patent.

The subject has also caught attention of academia. Prof Frederic Abbott recently spoke on the subject at the ASEAN competition authorities' summit in Kuala Lumpur. Going forward, the pharmaceutical industry will now have to deal with new frontiers of divide. The competition authority will become a regular feature in their battle between competition and exclusivity, not just for mergers and acquisitions.

## Questions and answers on article

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**Q.** Can you predict how this will play out over the next 2-3 years.

**Ans.** The innovator companies will face increasing pressure to allow development of the bio-generic version to ensure access to medicines at affordable prices.

**Q.** Do you think it will slow development successfully or will regulators and governments look to combat this, and the innovators will have to change tact again.

**Ans.** No, it will not slow development of bio-generics. The regulators and the governments will take on the innovators and force them to facilitate development of bio-generic versions.

**Q.** A paragraph or two on the implications of this would be hugely interesting.

**Ans.** FDA Commissioner, Dr Scott Gottlieb's statement to CNBC is very interesting. He was categorical that the FDA has to intervene without waiting for action by FTC. The reality that the hawks among the innovator

companies will never give up is evident from their behavior. They spend millions of dollars on public relations campaign to be seen as promoting access to medicines, but actions are inconsistent with what they wish to be seen. This dichotomy and its exposure have made pharma and biotech companies appear as the worst of the lot.

**Q.** Could it even be the case that some generics companies stop development all together as the barriers become too high? (I am just speculating). Or alternatively, how the competition authorities and conventional drug regulators might interact (if at all) – will they be on the same side or perhaps operating against each other.

**Ans.** I do not think that bio-generic companies will back out. FDA Commissioner's statement will encourage them to be more aggressive than they have been so far. The FTC has already conveyed that it is contemplating launching a formal investigation. Thus, both drug regulator and the competition authorities will be on the same side.

## References

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Squawk Box, CNBC

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