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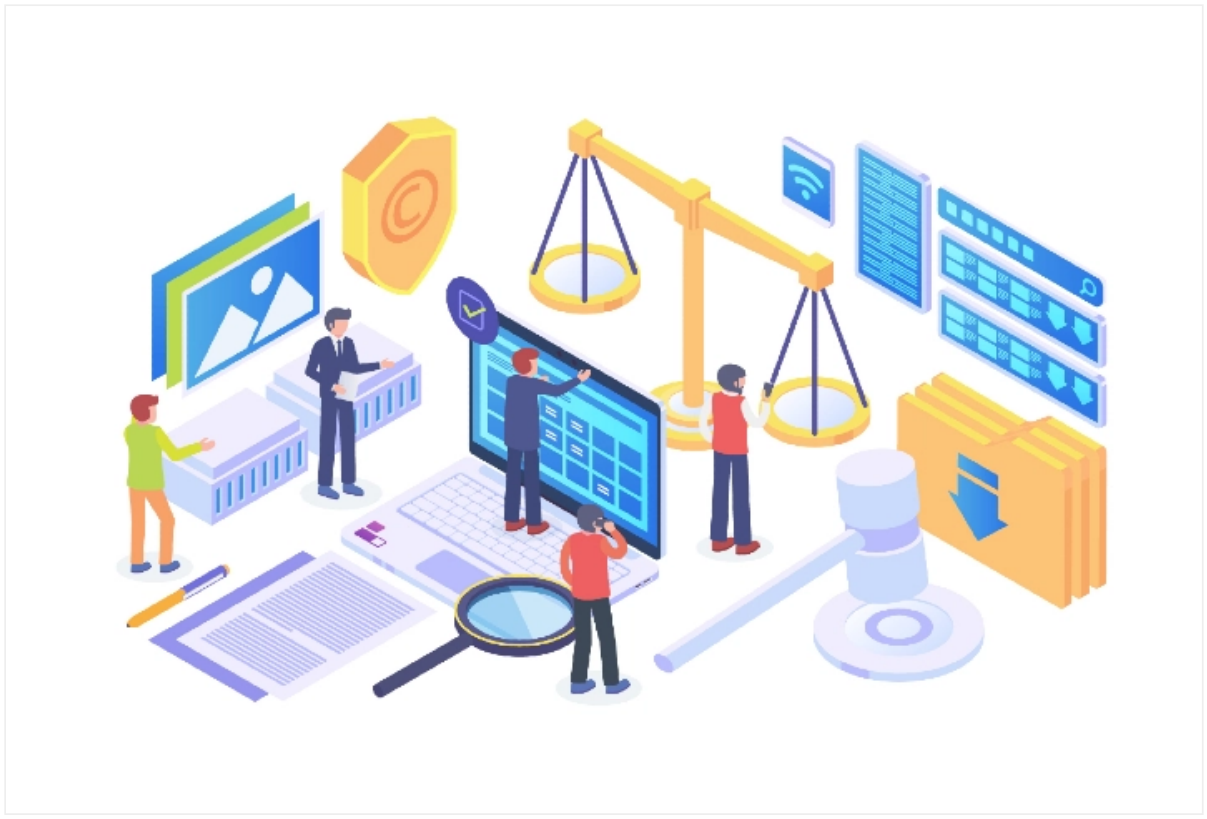
Regulatory Q&A: US patent law and The Orange Book



By Simon Wentworth

& Kelly Del Dotto

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This week Kelly Del Dotto, principal at USA-based patent firm Fish & Richardson P.C., provides context on the all-important Orange Book.

A key part of the patent landscape, the Orange Book provides a reference list of therapeutics that the US Food and Drug Administration (FDA) has approved, making it convenient for physicians to find generic equivalents.

The Pharma Letter asked Ms Del Dotto, an intellectual property and life sciences litigation attorney, for an overview of changes made under the recent Orange Book Transparency Act, as well as an insight into potential exclusivity changes under consideration by the US Congress.

What is the Orange Book and its significance within the Hatch-Waxman framework?

The Orange Book is a list of approved drug products that FDA is required under the Hatch-Waxman Act to make publicly available.

It includes information on the brand-name drugs for which New Drug Applications (NDA) have been approved, generic drugs for which Abbreviated New Drug Applications (ANDA) have been approved, patents covering the listed drugs with the patents' expiration dates, as well as regulatory exclusivity information.

Put simply, the Orange Book provides a public notice function for the patents that cover FDA-approved drugs and/or methods of uses for those drugs.

What are the key changes in the recent Orange Book Act?

The Orange Book Transparency Act of 2020, commonly called the Orange Book Act, largely codified in statute pre-existing federal regulations, although it does provide some helpful guidance.

One key change is that the NDA holders previously had to notify FDA "promptly" of a negative decision from the Patent Trial and Appeal Board (PTAB), or court.

The Orange Book Act clarified what prompt notice means, now requiring NDA holders to notify FDA within 14 days of a decision of cancellation or invalidation of an Orange Book-listed patent by the PTAB or court.

How might changes to the types of patents that are listable in the Orange Book affect innovative drugmakers and generic companies?

Almost any change to the Hatch-Waxman provisions will impact both branded and generic companies alike.

Planning for generic entry on the branded side starts years before any exclusivities expire and generics can enter the market. Similarly, generic companies can target branded drugs for generic development years before they file their ANDA.

So any changes in the legislative framework can affect both branded and generics' companies' market forecasting and strategic planning.

Expanding what is listable in the Orange Book may benefit innovative drugmakers because, now, prior to generic entry, the generic applicant would have to go through the certification and notice process as well as potentially be subject to a 30-month stay for FDA approval.

Conversely, removing certain types of patents from the Orange Book may benefit generics because then the generic companies do not have to go through the statutorily required notice requirements.

The FDA has made a number of legislative suggestions in its recent budget proposal, including amending the 180-day patent challenge exclusivity provision. What would be the impact of this be?

FDA raised a concern with the current 180-day exclusivity provision for first-to-file generic applicants, stating that the "exclusivity is often 'parked' by first applicants who either receive approval but do not begin marketing for extended periods of time following approval, or by first applicants who delay receiving final approval of their ANDAs for extended periods of time."

To address that, the FDA is recommending that Congress amend sections 505(j)(5)(B)(iv) and (D)(i)-(iii) of the Food, Drug, and Cosmetic Act to allow FDA to approve subsequent applications "unless a first applicant begins commercial marketing of the drug," triggering the 180-day exclusivity period.

Until the draft statutory language is provided, it is difficult to understand what the impact of these proposed changes will be.

What are the most common types of litigation and litigation strategies related to listable patents in the Orange Book?

The Hatch-Waxman amendments allow for listing of a patent which "(I) claims the drug for which the applicant submitted the application and is a drug substance (active ingredient) patent or a drug product (formulation or composition) patent; or (II) claims a method of using such drug for which approval is sought or has been granted in the application."

But these aren't the only patents that can be litigated, and in a Hatch-Waxman case, you can assert patents that can be listed in the Orange Book, but you can also assert patents that cannot be listed such as process or metabolite patents.

There is a jurisdictional difference, however, over Orange Book-listed patents which create an artificial act of infringement under 35 U.S.C. § 271 and non-Orange Book-listed patents which a plaintiff may have to assert declaratory judgment claims for.

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