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the compound, and then file a continuing application na
covering the active drug agent that is expected to beco
approved product. This will result in the granting of two
with the same expiration date both covering the approve
uct. The first one will be "good" as it is broad and the seco
be "strong" as it is narrow.

The reason the compound patent is the best pharmac
patent is that it covers a drug product no matter how it is
lated, no matter how it is made, no matter what it is sold
no matter what use it is put to, as long as it contains the
ed compound. According to a recent Court of Appeals de
which overturned a lower court ruling on this issue (*Smi*
v Apotex, CAFC 2004), even the *amount* of that compo
not important, so that a drug product will infringe a com
patent even if it contains only a trace of the patented com
and even if an infringer did his best to try to keep that tra
of his product.

Medical Use Patents

The next most valuable type of pharmaceutical patent is a
cal use patent. This type of patent covers the approved m
use or indication of an approved drug product. It can also
unapproved medical uses. Typically, a medical use clai
treatment of a specific disease or condition is directly infr
only by a patient with that disease or condition or by the
tor for prescribing it, but not by the drug product manufac

What about infringement of off-label patents, that is, patents which cover a medical use *not* on the label of a drug product, since many drugs today are used extensively by doctors for off-label medical uses? That is a more difficult question to answer and that is one reason why a compound patent is better than a use patent, since there is infringement with a compound patent regardless of the use or whether the use is approved or not.

There are two general situations in which off-label infringement occurs. The first is off-label use where an infringing product is labeled and sold for a given use, but prescribed by physicians for a patented use not on the FDA approved label. In order to show inducement of infringement, the patent owner would have to provide evidence that the drug manufacturer knew of the off-label use and actively induced others to infringe. This tends to be an issue that revolves around obtaining evidence of knowledge and intent of the drug manufacturer including evidence of any overt acts to induce infringement. Examples of activities that could suggest active inducement are any promotional or informational activities for the off-label use by the manufacturer or by third parties connected to the manufacturer in one way or another, such as statements by company sales people, company website references to the indication or educational programs for physicians to teach the off-label use that are directly or indirectly sponsored by the manufacturer.

The second off-label use is in the context of an abbreviated new drug application (ANDA) (see page 50 under Types of

federal legislation make it clear that innovators can no lo
list off-label patents in the Orange Book. This is discusse
more detail in future chapters.

However, where a generic company tries to obtain labe
for less than all the approved uses for an innovative drug,
one of those uses is patented by the innovator, the innov
may still sue for infringement. In a recent case, (*Takeda v V*
son Pharmaceuticals, 2003), a lower court ruled a patent ho
may sue a generic company for inducing infringement of its
patent based on the filing of an ANDA even though the ap
cation was pending and no sales had been made.

Formulation Patents

The third basic type of patent for drug products is a formulat
patent that typically covers the active drug agent in the spec
formulation for use in the body. Sometimes, the formulation p
ent covers a unique excipient such as a stabilizer or preservat
used in the formulation. A formulation patent offers the le
desirable patent protection because typically it can be avoi
by using a different formulation. However, in the context of
ANDA submission for a generic drug, a formulation patent,
matter how narrow, may be ideally suited to prevent copying
the drug by a generic company.

This is because of the regulatory requirements for pharmace
tical equivalence and bioequivalence that a generic drug mu
meet. While a generic drug is allowed to have minor changes

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