II. Background

A. Markush type claim

There are several special claim formats, such as Jepson type claims, product-by-process claims, means-plus-function claims, step-plus-function claims, Markush type claims, and so on. Markush type claims can be used where no generic term exists which describes the desired individual species and includes claim members selected from a group.[28] For example, "a metal selected from the group comprising nickel, palladium, and platinum". The purpose of a Markush type claim is to describe a group of individual elements which have common features or similar properties, or which have an equivalent basis for categorization in the same group.[29]

The downsides of broad Markush type claims are that they can be difficult to search, increase the prosecution time and examination errors, undermine their status as the prior arts, and be unclear in their scope of protection.[30] Advantages of Markush type claims include that they can offer broader protection for the patentee, be easier to file as one multinational patent application rather than several separate patent applications, and provide the licensor with a better basis for cross-licensing agreements with licensees who own improvement (selection) patents used the licensor's invention.[31] Almost all pharmaceutical patents are basically drafted with Markush type claims. Since selection patent claims, by nature, are directed to a specific species or a subgroup thereof which falls within the prior wider genus, it has been considered whether the disclosure in Markush type claims invalidates a later selection patent.

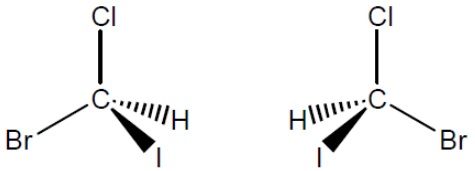
B. Enantiomers and Related Patents

Enantiomers are compounds which have the same molecular formulas but the special structure of one compound is the nonsuperimposable mirror image of the other,

28 *See, e.g.*, Alan L. Durham, Patent Law Essentials: A Concise Guide 61 (2nd ed. 2004).
29 *See, e.g.*, Edward H. Valance, *Understanding the Markush Claim in Chemical Patents*, 1 J. Chem. Doc. 87, 87-88 (1961).
30 *See* Lucille J. Brown, *The Markush Challenge*, 31 J. Chem. Inf. Comput. Sci. 2, 3-4 (1991).
31 *Id.* at 2-3.

thereby being called "chiral" which is a Greek term meaning "handedness".[32] The enantiomers are not identical to each other, but have at least one "stereocenter" which is a carbon atom with four different groups attached.[33] A "racemic mixture" or a "racemate" refers to a mixture of the R and S enantiomers which is normally produced through a chemical reaction which prepares a chiral compound from an achiral compound in normal conditions.

Figure 2:
Example of enantiomer-bromochloroiodomethane



Enantiomer patents can be defined as patents which claim selected individual enantiomers of a chiral drug which was previously disclosed as racemates in the prior art, e.g. in a basic patent. For this reason, an enantiomer patent can be categorized as claiming a selection invention.[34] Enantiomer patents are normally filed later than the filing date of basic patents, therefore the expiry dates of enantiomer patents are later than that of the corresponding basic patent. The top three best-selling global drugs from 2007 to 2009 are drugs of single enantiomers which are claimed in enantiomer patents, namely, Lipitor (Atorvastatin calcium), Plavix (Clopidogrel bisulfate), and Nexium (esomeprazole magnesium).[35] The importance of enantiomer patents is reflected in the upcoming 'patent cliff[36]' threat by the expiry of enantiomer patents of blockbuster chiral drugs.[37]

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32 *See generally* Johnson. A. William, Invitation to Organic Chemistry 612-613 (1999).

33 For example, two different mirror-imaged forms are a „right handed form" and a „left-handed form" In Figure 2, the carbon atom in the center is a stereocenter to which four different groups has been attached, namely Br, Cl, I, and H. Some compounds having more than two chiral centers result in multiple possible three-dimensional arrangements which are known as diastereomers.

34 A basic patent can also be referred as a broader patent or an earlier patent.

35 IMS Health, Top 15 Global Products 2009, available at http://www.imshealth.com/deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/Global_Top_15_Products.pdf.

36 *See* Peter Mansell, *Who is afraid of the patent cliff?* 1 SCRIP Executive Briefing 1, 1–16, (2008) (explaining that "patent cliff" is a term for the loss of revenue which occurs when the monopoly granted by patents is lost and the generic versions of drugs enter into the market. It is expected that the patent cliff reaches its peak in 2010-2011 as patents of many blockbusters including SanofiAventis' Clopidogrel, Pfizer's Atorvastatin, and others expire.).

37 *See* Israel Agranat et al., *The Strategy of Enantiomer Patents of Drugs* 15 Drug Discov. Today 163, 169 (1999).

The validity of enantiomer patents has often been challenged by generic pharmaceutical companies on the grounds of lack of novelty, lack of inventive step, lack of utility, double patenting, and insufficiency of disclosure.[38]

38 *Id.* at163.