Drug Development Implications of *Schering v. Geneva*

The Federal Circuit recently rendered a decision on the validity of metabolite drug patents in *Schering Corp. v. Geneva Pharm. et al.*, No. 02-1540 (Fed. Cir., Aug. 1, 2003). The case arose from a patent infringement action initiated by Schering Corp. against Geneva Pharmaceutical, and several other generic pharmaceutical companies. Geneva had applied for an abbreviated new drug application (ANDA) for Claritin® (loratadine). As part of the ANDA application process, Geneva had to make certifications with respect to each of Schering's patents listed in the Orange Book for Claritin®. One of these patents claimed descarbethoxyloratadine (DCL), the active metabolite of loratadine. DCL is separately approved by FDA and marketed as Clarinex®. Geneva filed a paragraph IV certification for the DCL patent, claiming that it was invalid or not infringed. The Federal Circuit agreed with Geneva and held that the compound claim covering DCL is invalid because it is anticipated by a patent covering the parent drug, loratadine. The court rested its holding on the fact that the metabolite would have necessarily formed in the patients who were administered the parent drug, and such administration, which was taught by the parent drug patent, predated the compound claim to the metabolite by more than a year.

While the Federal Circuit suggested various ways in which patent owners could modify their compound claims covering metabolites, none of the suggested ways can ameliorate the potential damage done to a company's investments in a metabolite product. Prior to the *Schering* case, pioneer pharmaceutical companies could have relied on a strategic pharmaceutical business plan wherein they could stagger patenting and marketing of a parent drug and its metabolite. Such staggering would have ordinarily extended the market protection rights for the parent drug and the metabolite. Accordingly, these companies secured patent claims covering both compounds, pharmaceutical compositions, selected pro-drugs and formulations containing the compounds, as well as treatment methods involving administration of the compounds. Any other competitor seeking to market a pharmaceutical product containing the parent or the metabolite would have been blocked by these patents.

After the decision in this case, however, the metabolite patents no longer have an economically viable claim to the metabolite compound. While it had always been the case that a competitor could patent an unobvious and unanticipated pro-drug of a metabolite that is covered by a compound claim, the competitor could not have marketed this pro-drug without infringing the compound claim covering the metabolite. Thus, before the *Schering* case, there was no such thing as a non-infringing pro-drug of a patented metabolite. After *Schering*, however, the invalidity of economically viable compound claims covering metabolites means that a competitor can now patent *and* market an unobvious and unanticipated pro-drug of the metabolite. From a chemistry point of view, designing and synthesizing such a pro-drug is not only feasible but it is also easily achievable. The competitor can also rely – at least in part – on the pioneer's data on the parent drug or the metabolite to gain FDA approval to market its non-infringing pro-drug. This scenario can take place even if the patent terms on the pharmaceutical compositions containing the metabolite and the associated treatment method claims are still in effect. Worse yet, in another scenario, a competitor can now patent and market a non-infringing pro-drug of the metabolite regardless of whether the patent term on the parent drug is still in effect. Under this scenario, the pioneer's business plan to stagger the marketing of the parent drug and the

metabolite would not only be preempted by this competitor, but the pioneer's market share for the parent drug itself would be eroded by the competitor's potentially superior drug.

Therefore, unless mitigating measures are taken at all steps of a pharmaceutical business plan involving parent and metabolite drugs, the holding of the *Schering* case will severely diminish the return on investment expectations that can be gained from such a plan. We have evaluated the market protection issues that the *Schering* case raises, and have identified strategies to address them. These strategies include patent, regulatory and data protection approaches to address concerns at various stages of development and commercialization. Please contact us if you would like us to assist you in assessing your risks or potential vulnerabilities regarding your pharmaceutical business plan, and to guide you on how to put in place mitigating measures to avert the adverse consequences engendered by *Schering Corp. v. Geneva Pharm.*

For assistance on this and other market protection matters, please contact your Ropes & Gray attorney.