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TO: Donald S. Clark
Office of the Secretary
Federal Trade Commission

FROM: Dr. Nahed Ahmed
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SUBJECT: FTC/DOJ Hearings on "Competition and Intellectual Property Law and Policy in the Knowledge-Based Economy"

I am Dr. Nahed Ahmed, Global Head of Productivity Portfolio and Project Management at Aventis. I have spoken about the pharmaceutical research process and the selection of projects as candidates for development at a number of industry events and have written on this subject as well.

As you consider the relationships between intellectual property protections and anti-trust law, I want to encourage you to pay very close attention to the important role that intellectual property protections play in the current model of drug discovery and development. Under this model, we have witnessed a huge transformation in the way we treat human diseases and conditions and have, as a result, recognized enormous improvements in life span and quality of life.

I ask you to consider the important role of patents and intellectual property protections in the review processes for research projects. All major pharmaceutical firms conduct portfolio reviews about once every year. During such reviews, a company usually employs a cross-functional review committee to examine the

current state of the portfolio and decide where the company will invest its resources during the coming year.

During this process, the cross-functional team is very well aware of the patent situation. Typically it is included in the summation that is presented when a company is making decisions about research investments. Discussions of patent strategy are fairly common in these meetings – in much the same way that one would discuss preparations for a regulatory review of a new product's dossier.

Patent status plays a big role in determining whether a company will or won't go with a project, because it directly affects the commercial value of a research program.

When we are forced to choose among multiple feasible research projects, we employ certain criteria at the last pre-clinical point – after this, the costs of a research project begin to escalate rapidly. The criteria are largely scientific in focus: Has the concept been proven? Do we have enough data? Are the models relevant to the disease?

These criteria must be viewed against other relevant considerations: Will it be commercially attractive? Do we expect changes in the marketplace or with competition against this product?

All of this adds up to an assessment of value: What is the net present value of a project? What is its associated risk? What can we say about the project's terminal investment? What value does it bring to the company with respect to cash flow? All of this must be evaluated dynamically, through scenarios that play out various "what if. . ." possibilities.

At this point, the idea is to terminate as many projects we can in Phase I and IIa so that we increase the probability of success for those projects we intend to pursue, given the financial and business limitations which are imposed upon us. Should we

enhance our presence in a given therapeutic area? Do we want more risk or less risk in our research and development portfolio? How much risk can we afford?

Most of the time these questions are raised in the context of a never-ending R&D budget gap. For a company like Aventis, these gaps are significant and often run in the hundreds of millions of dollars, which means choosing among promising research projects that have met rigorous scientific criteria but can't be pursued simply because we don't have enough money to fund them all.

What happens to these projects? Some can be considered for out-licensing, but only if there is a buyer who can cover the cost of development or co-development where we essentially "lease out" a compound for Phase I and II development. Leaving a compound fallow also reduces its commercial value because the market is constantly changing and often little patent protection remains for the compound. A compound or project that has not received attention for several years is likely to be abandoned.

If patent protection is reduced, we are not going to be able to work on as many projects and will not be able to seek out cooperative projects outside the company. Technically viable projects would no longer be commercially viable.

A reduction in patent protection must also be evaluated against other forces affecting the way we do research. Whether you accept an $800 million per drug estimate or not, the costs of doing research have increased significantly in the last three or four years. Fewer new compounds are being approved. Cycle times are predicted to increase, pipeline sizes are decreasing, and success rates are falling, so it is taking longer and costing more to develop a drug today than it did a few years ago.

To keep things afloat, companies will be attracted to line extensions rather than developing new chemical entities. With a line extension, we know a great deal about the compound because its parent is already on the market, which helps reduce cost and cycle time.

With a new chemical entity, less is known and more has to be studied, so a reduction in patent protection could reduce the incentive to work on them. In the same way, the so-called “me too” drugs are safer, faster, and more cost effective for the developer as an incremental improvement rather than an original product.

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