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September 14, 1998

Commissioner of Patents and Trademarks
Box 8
Washington, DC 20231

Attention: Scott A. Chambers
Associate Solicitor

Gentlemen:

This is in response to the request of the Patent and Trademark Office ("PTO") for comments on the interim guidelines for the examination of patent applications under the written description requirement of 35 USC 112, paragraph 1 ("Interim Guidelines") set forth at 63 Fed. Reg. 32639, 1212 OG 15.

I am a sector patent counsel for Novartis Corporation, the United States holding company for Novartis AG, Basle, Switzerland. Novartis AG was created in December 1996 by the merger of Sandoz AG and Ciba-Geigy AG. The Novartis companies will hereinafter be collectively referred to as "Novartis". Novartis is one of the world's largest life sciences companies with operations in the pharmaceutical (ethical, generic and over-the-counter), agrochemicals, seeds and nutrition industries. Among Novartis' operating companies in the United States are Novartis Pharmaceuticals Corporation, SyStemix, Inc., Genetic Therapy, Inc., Novartis Consumer Health, Inc., Geneva Pharmaceuticals, Inc., CIBA Vision Corporation, Novartis Crop Protection, Inc., Novartis Seeds, Inc., Novartis Animal Health US, Inc., Novartis Nutrition Corporation and Gerber Products Company. Biotechnology plays a major role in most of Novartis' operations, particularly ethical pharmaceuticals and seeds, and three of the company's operating companies, SyStemix, Inc. and Genetic Therapy, Inc. in the United States and Imutran Ltd. in Great Britain, are biotechnology companies. In addition, Novartis, through its foundation, is committing hundreds of millions of dollars over the next ten years to establish and fund two genomics institutes in the San Diego, California area; one institute will focus on plant genomics and the other on genes that cause diseases in man. Over the next ten years \$600 million will be spent on the plant genomics institute alone. This is above and beyond what Novartis' operating companies will spend on biotechnology.

The views expressed in this letter are my personal views as well as those of many of my colleagues both here in the United States and abroad but they are not necessarily those of Novartis as a whole.

In the field of biotechnology, Novartis' primary patent goals are to obtain exclusivity for what is intended to be commercialized and minor variations thereof and to prevent other companies from blocking it from utilizing various areas of technology in its extensive research programs.

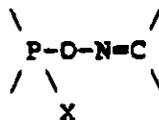
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and from extracting from it large sums of money in the form of up-front lump sum payments or as royalties on down-stream products, i.e., products invented as a direct or indirect result of the use of the technology (in contrast to products that actually embody the technology), for the privilege of using of the technology. It is not a primary goal of Novartis' patent policy to block others from utilizing basic technology. Novartis' goals admittedly color its views.

I oppose the Interim Guidelines to the extent that they sanction the patentability of claims covering full length molecules by virtue of the use of "comprising" language based upon the determination of the structure of only a small fragment of the molecule, e.g., an EST. The discovery or invention of a fragment of a molecule should not entitle one to claims that embrace every conceivable molecule that contains that particular fragment. It is, for all practical purposes, an incomplete invention.

In Subsection B of Section II of the Interim Guidelines a distinction is made between, for example, the claim "A gene comprising SEQ ID NO:1." and the claim "A DNA comprising SEQ ID NO:1." where SEQ ID NO:1 is only a fragment of the complete molecule. According to the Interim Guidelines, the former raises a question of compliance with the written description requirement whereas the latter does not. Frankly, I fail to appreciate the distinction. If, as set forth in the Interim Guidelines and I agree, the former is rejectable as based upon a specification that does not comply with the written description requirement, so is the latter. The mere use in the preamble of the clearly broader term "DNA" cannot possibly turn an unpatentable claim into a patentable one.

Over the years the PTO has consistently, and, it is submitted, properly, rejected claims to chemical compounds wherein only a portion of the structure is set forth as well as claims to compositions containing such compounds, i.e., dangling valence claims. See, for example, Ex parte Diamond, 123 USPQ 167 (POBA 1959). Claim 1 on appeal in Diamond was directed to "[a]n insecticidal composition comprising a pesticidal adjuvant as a carrier and an insecticidally active compound containing the characteristic



grouping wherein X is a member of the group consisting of oxygen and sulfur." According to the Board, "this type of claim is improper because indeterminate in scope and generally broader than any possible supporting disclosure."

Claims such as "[a] DNA comprising SEQ ID NO:1" are analogous to dangling valence claims which, for many years, have been deemed to be unpatentable. Ex parte Diamond, supra. I can see no real distinction between open-ended DNA claims and dangling valence claims. All such claims are defined in the sense that one of ordinary skill in the art would at once know whether any given compound did or did not fall within the claim and could also write down the structures of numerous members of the

claimed genus. However, just as dangling valence claims are unpatentable, so should be open-ended DNA claims.

Admittedly, in the polymer art it is conventional to merely define the polymer's recurring units and not to specify the end groups. However, in the case of a polymer the end groups constitute a de minimus portion of the molecule and have no appreciable effect on the use of the polymer. Consequently, any analogy made between open-ended polymer claims and open-ended DNA claims fails.

An analogy has also been made between open-ended DNA claims wherein only the structure of the EST is set forth and open-ended claims directed to a novel cab of a tractor trailer truck. However, I respectfully submit that analogy fails because the cab is itself a complete article and, moreover, is a complete invention whereas an EST is neither a complete article (but only a fragment of an article) nor a complete invention. Since the cab itself is a complete article as well as a complete invention, open-ended claims that embrace it properly embrace it alone or when attached to one or more trailers. In contrast, since an EST is neither a complete article nor is it a complete invention, one should not be able to claim it, particularly with open-ended claims that embrace every conceivable DNA of which it is an integral part.

According to Subsection B of Section II of the Interim Guidelines, a claim to "A DNA comprising SEQ ID NO:1" meets the written description requirement and concludes that it does so because "one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus." *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1998), is cited in support.

I respectfully disagree. Given the disclosure of a DNA sequence in the form of an EST of n nucleotides, it is of course clear that one of ordinary skill in the art can readily write down the eight members of the genus having $n + 1$ nucleotides (each of the four natural nucleotides can be added at either terminus). However, when just ten nucleotides are added to the original EST, there are 11,534,336 possibilities, when twenty nucleotides are added, there are nearly 2.2×10^{13} possibilities, and when n is 100, a mere doubling of the length of the original EST would give more than 1.623×10^{62} possibilities, an astronomical, if not virtually infinite, number of possibilities. Note that just 10^{36} possibilities was deemed to be "a nearly infinite number of possibilities" in *In re Bell*, 26 USPQ2d 1529 (Fed. Cir. 1993). The formula for calculating the number of possibilities is $4^n \times (m + 1)$, where m is the number of nucleotides that are added to the original DNA containing n nucleotides. It is all very well to say that some of these possibilities could be written out, but that should not mean that the applicant was "in possession of" such an enormous genus.

And of course the claimed genus goes far beyond this in that it includes DNA sequences which are not just double the size of the original EST of one or two hundred bases, but which may be thousands or even millions of bases long. The CAFC in *University of California v. Eli Lilly and Co.*, supra, at 1406, column 2, lines 6-14, stated that "[a] descrip-

tion of a genus of cDNAs may be achieved by means of ... a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus" (emphasis added). The common sequence characterizing the genus is not and cannot be considered to be a "substantial portion" if the open-ended claim covers sequences much longer than the original structurally defined EST.

As set forth in Section I of the Interim Guidelines, a primary policy objective of the written description requirement is to convey to one of ordinary skill in the art the information that the inventor had invented the claimed subject matter, i.e., that the inventor was in possession of the claimed invention. However, the disclosure of only a small fragment of a molecule simply does not convey to one of ordinary skill that the inventor had invented and was in possession of large molecules of which that fragment is but a tiny part.

Perhaps the real objection to open-ended DNA claims is a question of utility rather than written description. The PTO has indicated that almost any utility will suffice for a claim to an EST, e.g., use in tissue typing or even use in forensic medicine. But even these vague utilities would be unlikely to be met if the length of the DNA sequence was greatly extended. Or could the applicant avoid this problem by setting an arbitrary upper limit to the length of the sequences claimed, such upper limit being large enough to include any likely complete gene?

A possible compromise is to permit applicants to use "consisting essentially" as the transitional phrase rather than "comprising", e.g., a claim reading "A DNA consisting essentially of SEQ ID NO:1." Such a claim would be limited to DNAs having the nucleotide sequence set forth in SEQ ID NO:1 plus minor additions at the 5'- and/or 3'-ends of the recited sequence.

For the foregoing reasons, I respectfully oppose the Interim Guidelines to the extent that they sanction the patenting of claims covering entire molecules by virtue of the use of "comprising" language based upon the determination of the structure of only a small fragment of the molecule.

In its request, the PTO set forth five issues with respect to which it was particularly interested in comments. I would like to briefly address these issues:

(1) The methodology employed, to the extent that I comprehend what is meant by "methodology", appears to be sound. However, it is far too early in the development of the relevant case law for the PTO to set forth more permanent Guidelines in this area. Rather, I propose that the published Interim Guidelines be replaced by Revised Interim Guidelines and that the preparation of more permanent Guidelines be deferred until the CAFC, if not the United States Supreme Court, hands down decisions that elaborate upon, construe, modify and/or overrule *University of California v. Eli Lilly and Co.*, supra, and/or decide intimately related issues not dealt with by that case. Note, in this connection, that the CAFC very recently declined to do so in *The Johns Hopkins University et*

al. v. CellPro, Inc., 47 USPQ2d ____ (Fed. Cir. 1998), on the ground that they had not properly been raised in the district court.

(2) Subsection D of Section II of the Interim Guidelines appears to omit an important factor in determining compliance with the written description requirement for a generic claim, viz., the disclosure of the claimed genus itself. A few species, even if disclosed in full compliance with the Interim Guidelines, rarely, if ever, constitute sufficient support for generic claims unless accompanied by a generic disclosure that is commensurate in scope with the claims. Even in the mechanical arts one cannot draft claims as broad as permitted by the prior art without a corresponding broad written description in the specification. *The Gentry Gallery Inc. v. The Berkline Corp.*, 45 USPQ2d 1498 (Fed. Cir. 1998), citing *University of California v. Eli Lilly and Co.*, supra.

(3) As for the scope of the Interim Guidelines, they are clearly limited to claims directed to amino acid and nucleic acid sequences although the principles set forth apply not only to all biotechnological inventions but to all inventions irrespective of the technology. Other than for plants and designs, we have but one patent law for all technologies.

(4) At the present time any expansion of the Interim Guidelines would be premature.

(5) The Interim Guidelines should have no significant impact on pending or future patent applications because they are, and ought to be, no more than guidelines; they do not have the force of law or even of rule. As guidelines, they are not binding upon the Board of Patent Appeals and Interferences or, for that matter, even the examiners. Moreover, it is ultimately for the courts, particularly the CAFC, to decide all major questions relating to patentability, not the PTO.

Feel free to contact me by telephone (908-522-6927), telefax (908-522-6955) or electronic mail (Melvyn.Kassenoff@group.Novartis.com) if you wish to discuss, or would like me to elaborate on, anything set forth herein or if you would like a Word 6.0 or 7.0 copy of this letter on a disk. A copy of this letter is being sent to you as a Word 6.0 attachment to an electronic message.

Respectfully submitted

Melvyn M. Kassenoff

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