E

WIPO

WIPO/ACE/3/9
ORIGINAL: English
DATE: April 28, 2006

WORLD INTELLECTUAL PROPERTY ORGANIZATION
GENEVA

# ADVISORY COMMITTEE ON ENFORCEMENT

## Third Session
## Geneva, May 15 to 17, 2006

CONSIDERATION OF INTELLECTUAL PROPERTY RIGHTS IN REGULATION AND CONTROL: ACTIVITIES OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC) [*]

*Document prepared by Prof. D. N. Akunyili,*
*Director General, NAFDAC Nigeria*

[*] The views and opinions expressed in this paper are those of the author and not necessarily those of the World Intellectual Property Organization (WIPO) or its Member States.

# CONSIDERATION OF INTELLECTUAL PROPERTY RIGHTS IN REGULATION AND CONTROL: ACTIVITIES OF THE NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

## INTRODUCTION

The topic "Consideration of intellectual property rights in regulation and control activities of NAFDAC" will highlight the activities of the National Agency for Food and Drug Administration & Control (NAFDAC) in actualizing its mandate which is to regulate and control foods, drugs and other regulated products with reference to intellectual property rights. This is carried out in tandem with the federal government policy of ensuring optimum public health alongside promotion of individual private investment. NAFDAC is not oblivious of the provisions of agreements on trade related aspects of intellectual property rights (TRIPS) which has not been domesticated in legal system of Nigeria. Be that as it may, the Agency has taken measures to ensure that its primary focus which is safeguarding public health as mandated by its enabling laws and consistent with national policy are effectively pursued.

The different forms of intellectual property namely, trademark and patents are relevant to the regulatory and control function of the Agency. While not primarily focused on enforcement of property rights, the Agency's concerns are on how claims and counterclaims on these issues affect its primary responsibilities. Being that its regulatory functions are product based, much attention is paid to trademark issues because of product identity. The onus of proof however lies on the claimants. From a regulatory standpoint, distinctiveness is the essence of a valid trademark. Whatever that detracts from this, will be a pure recipe for confusion and a negation of the right of a consumer to make informed choice.

Patents which are mostly drug related are recognized in so far as they are consistent with the national drug policy. The main objectives of the national drug policy are to make effective, safe and low cost drugs available and affordable to meet the needs of the entire population and to ensure that drugs are of good quality and used rationally.

Misbranding or counterfeiting of regulated products is a direct consequence of violation of intellectual property rights. The prevalence of violations of these rights and the need for proper management of intellectual property regime offer compelling reasons for enforcement activities within a legal regulatory framework.

## THE LEGAL REGULATORY FRAMEWORK

The National Agency for Food and Drug Administration and Control (NAFDAC) is a body corporate established by the NAFDAC Act of 1993 now listed in the Laws of the Federation of Nigeria 2004 as Cap NI.

NAFDAC is empowered under the enabling law to amongst other things: regulate and control the importation, exportation, manufacture, advertisement, distribution, sale and use of food, drugs, cosmetics, medical devices, packaged water and chemicals, generally know as regulated products.

The Agency is mandated to under take the registration of regulated products. Related to this, is the recognition of intellectual property rights in evaluation of data and products submitted for marketing authorization.

Under the provisions of various regulations and related guidelines on registration, the submission of evidence of ownership of trademark is a condition precedent for the registration of branded regulated products. Although, whenever any trademark right is in conflict with any regulations or requirements of the Agency, the latter will supercede (e.g. the issue of look alike and sound-alike). This is informed by the need to ensure that the Agency's core mandate which essentially is the protection of consumers by ensuring the use of only safe, wholesome, quality and properly labeled regulated products is effectively adhered to.

Having recognized counterfeiting and circulation of fake products as a health issue as well as an infringement of intellectual property rights, the Agency has as part of its Enforcement Directorate, a police force squad that is responsible for ensuring that its regulations and guidelines are adhered to. They are to arrest any person suspected of committing an offence under the national law on counterfeiting and collation of files for prosecution by the Agency's legal team.

## MEASURES TAKEN BY NAFDAC IN THE FIGHT AGAINST THE INCIDENCE OF COUNTERFEIT REGULATED PRODUCTS AND TO PROTECT INTELLECTUAL PROPERTY RIGHTS.

### PUBLIC ENLIGHTENENT CAMPAIGNS

NAFDAC is empowered under section 14 of its enabling law to apply the resources at its disposal to publicize and promote its activities. This includes enlightenment campaign, which remains one of its most effective strategies in combating product counterfeiting and ensuring effective protection of intellectual property rights.

This is the Agency’s most effective strategy involving dialogue, education and persuasion.

It is sustained by using:

- Print and electronic media such as jingles, alert notices, erection of billboards, publication of differences between identified fake and genuine products in the national dailies, etc.

- Production of many other publications, fliers, leaflets and posters, both in English and Vernacular languages;

- Workshops, seminars and meetings have been conducted for most stakeholders.

- Mobilization campaign for rural dwellers is on- going.

The campaign has also been extended to Nigerian High Schools in order to catch them young, by organizing annual competitions and prize giving ceremonies on their understanding of the ill effects of counterfeit regulated products on the society. The Agency has established

NAFDAC Consumer Safety Clubs in most schools in Nigeria. These activities are further geared towards educating the young ones on the dangers of counterfeit regulated products, inculcating in them the value of genuine products and encouraging them to join NAFDAC in this fight.

Enlightenment and the resultant change of heart are result-oriented and complementary to prosecution, which the Agency had used over the years with little success.

Above all, NAFDAC enlightenment campaigns have greatly empowered the public to recognize and reject counterfeit regulated products, thereby enhancing public awareness of intellectual property rights.

ADVOCACY AND COLLABORATION WITH RELEVANT STAKEHOLDERS

In line with one of the functions as contained in section 5 (r) of its enabling law, which empowers the Agency to liaise with relevant establishments within and outside Nigeria in pursuance of its mandate, it has working relationship with the Police, Customs, the Ports Authority, the National Drug Law Enforcement Agency, the Standards Organization of Nigeria etc. This type of collaboration is to address areas of overlapping functions, which counterfeiters are wont to exploit. Good collaboration enhances effective enforcement. This collaboration has resulted in the designation of exclusive ports of entry for regulated products and release of cargo manifests from the ports authority, shipper's council and all airlines to the Agency for comprehensive inspection of cargo.

Moreover, there are various administrative bodies set up by the government where stakeholders meet to formulate policies and review strategies for combating the incidence of counterfeit products.

Also, one of the gains of the Advocacy and collaborative efforts is an understanding between the Agency and Central Bank of Nigeria to require clearance permit from NAFDAC prior to issuance of foreign exchange to manufacturers and importers of pharmaceutical products to ensure that they are genuine and authorized by NAFDAC.

The Agency has various understanding with relevant regulatory agencies such as the United States Food and Drug Administration (USFDA) aimed at pursuing areas of collaboration in the area of information exchange, staff training and technical assistance.

PARTICIPATION AND COLLABORATION WITH THE LEGISLATURE

The Agency has had several meetings with members and relevant committees of the two legislative houses of the National Assembly in Nigeria namely: the House of Representative and the Senate in order to strengthen the Agency's laws on counterfeiting of products and its regulatory framework among other things. In this regard, a draft bill on NAFDAC has been forwarded to the legislature which is currently receiving attention. The Agency has made various contacts and hopes to diligently follow-up the passage of the bills and its eventual assent by the President of the Federal Republic of Nigeria.

COLLABORATION WITH THE BAR

NAFDAC has continued to collaborate with the Nigerian Bar Association due to the strategic role they play in the administration of justice. The Agency has honoured several invitations

from them to address their members on the need for effective fight against counterfeit regulated products. For the most part, some of the frivolous and ill-motivated applications for injunctions restraining the Agency from dealing with counterfeiters are devised and pursued by lawyers on the prompting of their unscrupulous clients. The Agency concedes the fact that a great number of gentlemen of the bar may not be aware of the dangers of counterfeit products, hence the Agency's desire to embark on advocacy drive.

Moreover, the Agency has called and keeps calling on the members of the Bar Association to bring their tremendous influence and clout to bear on the legislature to ensure that the laws particularly in the area of sentencing of convicted counterfeiters, who get very minimal sentence for the commission of this very dangerous class of offences, are reviewed.

COLLABORATION WITH THE JUDICIARY

Following the massive enlightenment campaign by the Agency, there is sudden national awakening that the issue of counterfeiting, which is tied to intellectual property rights, is a major public health issue.

Indeed it has become a national issue. The Agency has also paid numerous visits to members of the judiciary to ensure the mounting of a conference for judges. This has resulted in the approval of a conference on counterfeit pharmaceuticals and by extension other regulated product by the National Judicial Institute, in association with the Agency, from 18th to 19th October 2006.

It is pertinent to mention that the National Judicial Institute is part of the Nigeria Judicial system entrusted with the training and continued education of judges. No doubt, this training, which will become a regular feature in the Agency's regulatory calendar, will enrich judges' knowledge of intellectual property rights and the scourge of counterfeit products. The exemplary decision of Honourable Justice Adeniyi Ademola sitting at the Federal High court in Kano Nigeria in the case of Federal Republic of Nigeria Vs Nonye Iwunze involving the counterfeiting of some drugs in the year 2005 wherein the Judge sentenced the offender on conviction to 5yrs imprisonment or option of fine to the tune of N500,000.00 on the two counts is worthy of mention.

BLUE PRINT ON ANTI-COUNTERFEITING

Realizing the complexity in the Intellectual property rights protection and the anti-counterfeiting campaign; the Agency published a blueprint to guide her in that regard. The blue print covers the year 2005-2010.

The strategy will address issues such as

- Sustained consumer awareness and education;
- Enhancement of partnership between the regulated product manufacturer/importer and NAFDAC especially in the areas of policy implementation, communication and introduction of modern security features;
- Provision of more effective legal framework for control and prosecution of counterfeiters;
- Collaboration with other stakeholders both nationally and internationally;
- Effective monitoring, surveillance and enforcement.

STAFF RE-ORIENTATION AND MOTIVATION

At the inception of NAFDAC present administration, the need for staff re-orientation was glaring. A total change of mindset and in fact, an organizational cultural revolution were needed.

The following measures were undertaken to reposition staff for better effectiveness:

- Retrenchment of corrupt, redundant and incorrigible staff;
- Induction training for new staff, specialized in-house and overseas training and computer appreciation courses were organized;
- Availability of information technology tools;
- Effective delegation of duties and staff empowerment ;
- Constant staff performance monitoring to ensure commitment and effectiveness;
- Hard work, dedication and integrity are adequately compensated to encourage staff;
- Leadership by example is highly emphasized;
- Streamlining and Strict Enforcement of Registration Guidelines.

NAFDAC has strengthened its registration processes with some administrative guidelines:

- All drugs must comply with laboratory standards and inspection requirements before they are registered;

- Renewal of registration of drugs is every five years, while herbal medicine is yearly;

- NAFDAC insists on fixing of NAFDAC REGISTRATION NUMBER on the label of all products to enable the public identify authorized drugs;

- Drugs can be imported for only ten years, after which the importer must start producing locally.

STOPPING THE IMPORTATION OF COUNTERFEIT REGULATED PRODUCTS TO NIGERIA AT SOURCE

To achieve this, NAFDAC has put in place some administrative guidelines which include:

- NAFDAC officials must inspect factories anywhere in the world before they register or renew registration for drugs, cosmetics, food and other regulated products to ensure Good Manufacturing Practice (GMP) compliance;

- NAFDAC has appointed analysts in India, China and Egypt who re-certify drugs before exportation to Nigeria;

- NAFDAC requires mandatory pre-shipment information to be provided by all importers before the arrival of their drugs;

- Nigerian banks insist on NAFDAC's clearance before processing financial documents for drug importers.

BEEFING UP SURVEILLANCE AT ALL PORTS OF ENTRY

NAFDAC has re-enforced the two new directorates of Ports Inspection and Enforcement for more effective surveillance at all ports of entry, and better enforcement activities respectively.

Hitherto, land and sea borders were major routes of importation. The Agency, having considerably intensified surveillance at these borders, drug counterfeiters resorted to using airlines. Consequently, NAFDAC issued a guideline that any aircraft that lifts drugs to Nigeria without obtaining NAFDAC's authorization from their clients would be grounded.

♦ Mopping Up Counterfeit Drugs Already in Circulation

Cognizance of Nigeria’s many porous borders, NAFDAC embarks on planned, continuous and sustained surveillance at all markets and retail outlets for drugs.

This led to closure of 2 major drug markets for 3 -6 months. To achieve high level of success with this mopping up exercise, NAFDAC has put in place the following administrative guidelines:

- Confiscation and subsequent destruction of drugs from sellers who fail to provide a proper invoice of purchase with full name and address, in order to trace the big time importers and distributors of fake drugs.

Faced with the frustrations of evacuating many lorry loads of fake drugs from warehouses on tip off without anybody accepting ownership, NAFDAC notified the public that whenever the importer cannot be traced, the landlord of the premises used for the storage of fake drugs would be arrested, with a view to tracing the fake drug importer. In one occasion in Lagos, it was only after the landlord of the warehouse was arrested that the fake drugs' owner surfaced.

Raids are regularly carried out on drug hawkers, and their drugs are confiscated and destroyed.

Fake drug dealers are also traced through reports from health professionals or victims and constant tip-off from the public.

Routine sampling, checking and testing of all NAFDAC registered drugs in circulation are routinely carried out.

MONITORING GMP OF LOCAL MANUFACTURERS

NAFDAC regularly monitors local manufacturers of drugs and other regulated products. Compliance directives are issued and enforced to the letter when lapses are observed. While prosecution is carried out when counterfeit regulated products are manufactured.

SOME OF THE ACHIEVEMENTS AND GAINS RECORDED

- Sanitized the food and drug industry and created a reasonably well regulated environment which have saved the lives of millions of Nigerians and boosted the economy by encouraging local industries, genuine importers and foreign investors.

- Immense public awareness resulted in the participation of all stakeholders in the promotion of food and drug regulation in Nigeria, and awakened the international consciousness that Nigeria is no longer a dumping ground for fake drugs.

- The level of incidence of fake/unregistered drugs has been reduced by about 90% from what it was in 2001.

- The production capacities of local pharmaceutical industries have increased tremendously, and 22 new drug manufacturing outfits were established in the last 5 years.

- The confidence of investors in the pharmaceutical industry has been reinforced as evidenced by the continuous upward movement in the share prices of the pharmaceutical companies quoted in the Nigerian stock exchange.

- Ban on made-in-Nigeria drugs has been lifted by other West African countries.

- Many Multinational Drug Companies are coming back to Nigeria due to improved regulatory environment.

- From April 2001 to January 2006, NAFDAC carried out over 100 destruction exercises of counterfeit and substandard products valued at about US$100 million.

- From 2001 to July 2005, over 1,000 raids were carried out on distribution outlets of fake drugs.

- 45 convictions were secured in respect of counterfeit-drug related cases, and over 56 cases are pending in courts.

- Sanctions on erring manufacturers and importers are increasing steadily. 2,226 in 2002; 3,178 in 2003; and 3,460 in 2004 and 4,132 in 2005.

- By reason of NAFDAC requirements the Nigerian Patent and Trademark Office is enjoying increased patronage evidenced with upsurge in application for Trademarks relating to NAFDAC regulated products.

CONCLUSION

There is no doubt that massive, sustained public enlightenment and education of consumers, importers, distributors and retailers of regulated products ensures willful compliance to regulatory requirements and enables the regulator focus on primary responsibilities which is safeguarding public health. While the responsibility for enforcement of intellectual property

right rests with the owner, the Agency has in place, procedures to check such infringements, such as counterfeits, as they impact on its regulatory functions.

There is need for the police, customs, the Patent and Trademark Office and other relevant government bodies to ensure that counterfeiters are not given any room to operate by exploiting any seeming overlap and conflict. The realization that the consumers should be protected and counterfeiters stopped from reaping the gains of their illegal and dangerous enterprise will galvanize the various bodies into closing ranks and forming a formidable force.

Finally, regional and international networking of stakeholders more particularly, the regulatory bodies should be encouraged for the exchange of information and adequate tracking and tracing of counterfeiters and their loot for appropriate sanction. This has brought to the fore the need for multilateral conventions on counterfeiting of regulated products, particularly drugs, which have become a lethal weapon of mass destruction in the hands of counterfeiters. This obviously will lead to effective enforcement of intellectual property rights and must be dealt with decisively.

[End of document]